Rhodes Business School

Leadership for Sustainability

WASTE MANAGEMENT IN THE PHARMACEUTICAL INDUSTRY – AN EVALUATION REPORT OF DR REDDY'S LABORATORIES

A half-thesis submitted in partial fulfilment for the requirements of the degree

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By

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Submission date: December 2012

DECLARATION

I, Tebogo Letsitsi, do hereby declare that this thesis is my own work and that all reference sources have been accurately acknowledged and documented. Further, this document in its entirety or in part has not previously been submitted to any University in order to obtain an academic qualification.

_____ _____

Tebogo Letsitsi Date: December 2012

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Integrative Summary

The integrative summary provides an introduction to the research evaluation report in the form of a case study, research area, presents the objective and concepts.

i. Background of Research Case Study

The pharmaceutical industry must worry about managing pharmaceutical waste as it poses a health risk to human beings and its presence in the environment can also contribute to loss of biodiversity. Ngwuluka, Ochekpe, and Odumosu (2011: 11259) state that "Pharmaceuticals, though used to treat and manage diseases, are poisons, which justify the growing concerns about their presence in the environment." Various forms of pharmaceutical waste exist, Ngwuluka *et al.* (2011) identified the following forms of pharmaceutical waste: Expired dosage forms, non-reworkable formulations, spilled pharmaceuticals, rejected active pharmaceutical ingredients, expired active pharmaceutical ingredients, and wastewater resulting from the water used for process operations during manufacturing and could come from the water used to clean equipment, pipes and floors, and would contain amongst other materials, chemicals and active pharmaceutical ingredients (APIs).

A review on the pharmaceutical industry and the progress they have made in environmental management by generating health, safety and environmental programs, preventing pollution, waste minimization, recycling and reusing materials, investing in projects and facilities to ensure environmental sustainability have been established (Berry & Rondinelli, 2000).

Dr. Reddy's Laboratories is an Indian based pharmaceutical company which imports, markets and sells medicines in South Africa. Dr. Reddy's has plans to set up a manufacturing plant in South Africa. The purpose of this study is to research waste management practices at Dr. Reddy's plant in India and to draw parallels between India's and South Africa's waste legislation. This is to enable Dr. Reddy's to review all aspects of its waste management systems, in order to revise where necessary and to improve the overall achievement of its waste management objectives in order to become a more sustainable organisation and to meet South African Waste legislation before setting up a plant in South Africa.

ii. Objective of the Evaluation Report

The purpose of this research is to evaluate and analyse the development and implementation of a waste management system in a pharmaceutical company, specifically Dr. Reddy's Laboratories. This is primarily to enable the company to review and analyse all aspects of waste management pertaining to pharmaceutical manufacturing and to revise or improve where necessary to ensure adherence to waste regulations as outlined by government. The following research goals have been also been identified:

- To identify and describe waste management practices at Dr. Reddy's Laboratories, on the inherent assumption by the researcher that the company has a successful waste management strategy that would need to be reviewed to identify areas of improvement before expanding manufacturing facilities into South Africa.
- To evaluate, assess and compare similarities and/or differences between the identified South African Legislation for Waste Management with those identified during research conducted at Dr. Reddy's Laboratories.

iii. Importance of the Research Conducted

Waste Management is important in that it not only removes from the environment, substances that can be harmful to humans and animals but it also enables an organisation to be more sustainable. According to Seadon (2010: i) “Integrated waste management is considered from a systems’ approach, with a particular emphasis on advancing sustainability”.

The study will provide guidance to senior management, shop floor managers and employees who work in Dr. Reddy’s manufacturing plants as well as overall employees at Dr. Reddy’s on how to successfully implement a Waste Management programme to enhance sustainability at the organisation and realise the benefits to the organisation of being more sustainable. Weybrecht (2010) identified the following benefits that companies could gain by adopting sustainable waste management practices: reduced costs, resource preservation, keeping up with legislation, enhanced reputation, business differentiation from competitors, and attraction and retention of quality employees, and customer need satisfaction amongst many other benefits.

This research needs to address the gap in analysing waste management practices (with more emphasis on waste treatment, waste minimisation, re-use, recycling and disposal), and implementation and understanding of waste management in the pharmaceutical industry as prior research was done mostly in other chemical industries and not to a large scale in the pharmaceutical industry. South African Waste Legislation, Indian Waste Legislation (as Dr. Reddy’s is based in India), as well as International Pharmaceutical Waste Management Guidelines, and International Pharmaceutical Good Manufacturing Practices provide a framework and benchmark of leading pharmaceutical waste management practices that can guide Dr. Reddy’s Laboratories’ leadership into integrating their waste management practices into their plans of setting up a manufacturing plant in South Africa.

iv. Research Methodology

This is evaluation research in the form of a case study and the data collection method employed is the conduction of a survey through questionnaires.

The evaluation research also involves a document analysis of the organisation's 2011 and 2012 annual reports, Dr. Reddy's 2010 Sustainability Report as well as literature compiled by the organisation's Corporate Communications Division. The research would also include review of existing literature on waste management.

v. Structure of Dissertation

This dissertation consists of three sections.

Section 1: The Evaluation Report

The section introduces the research area, provides the objectives of the research, provides contextual background information and describes the rationale for conducting the research. This section further describes Dr. Reddy's waste management practice as outlined in relevant company documentation; it is also intended to highlight the specific waste management processes that were followed in the formulation and implementation of the waste management strategy.

This section further describes the sample and presents the results of the survey, where the results are collated and reviewed in the context of the criteria set in the South African Waste Legislation, Indian Waste Legislation, as well as in International Pharmaceutical Waste Management Guidelines, and International Pharmaceutical Good Manufacturing Practices.

The overall findings of this case study suggest that although management at Dr. Reddy's are satisfied with waste management practices and results achieved at it manufacturing plant, there is however dissatisfaction amongst employees who believe the organisation has not successfully disseminated information and sufficiently trained them on waste management policies, processes and practices. There is therefore a desire amongst employees to be trained and to see the company improve on its waste management processes, this desire is a very important attribute as it indicates that employees at Dr. Reddy understand and are

committed to the importance of waste management. Future research should be conducted to measure the legal impact of non-compliance to legislation governing waste management in the pharmaceutical company.

Section 2: Literature Review

The objective of the literature review is to provide a critical assessment and evaluation of previous research in the field of waste management in general as prior research was done mostly in other industries and not to a large scale in the pharmaceutical industry. The literature review evaluates the key elements of an effective waste management strategy implementation and is followed by a review of literature pertaining to the description of Pharmaceutical waste.

Section 3: Research Methodology

This section presents a description of how the work in this research was conducted. It presents the research process followed in compiling this case study, represented by the aims and objectives, research methodology and design, data collection techniques and data analysis.

vi. REFERENCES

BERRY, M.A., RONDINELLI, D.A., 2000. Environmental Management in the Pharmaceutical Industry: Integrating Corporate Responsibility and Business Strategy. *Environ. Qual. Mange.*9:21-25.

GUBA, E.G., LINCOLN, Y.S., 1994. Competing Paradigms in Qualitative Research. In Denzin, N.K. and Lincoln, Y.S. (5ed). *Handbook of Qualitative Research*. London: Sage Publications.

NGWULUKA, N.C., OCHEKPE, N.A., ODUMOSU, P.O., 2011. An assessment of pharmaceutical waste management in some Nigerian Pharmaceutical Industries. *African Journal of Biotechnology*, 10, 54: 11259-11268.

SEADON, J.K., 2010. Integrated Waste Management, Doctor of Philosophy Thesis, The University of Auckland, and Auckland, New Zealand.

WEYBRECHT, G, 2010, *The Sustainable MBA: The Managers Guide to Green Business,* West Sussex, England: John Wiley & Sons Ltd.

1 Section 1 – Dr. Reddy's Laboratories Evaluation Report.

The section introduces the research area, provides the objectives of the research, provides contextual background information and describes the rationale for conducting the research. This section further describes Dr. Reddy's waste management practice as outlined in relevant company documentation and presents the results of the survey conducted amongst Dr. Reddy's employees.

1.1 Abstract and Introduction

Dr. Reddy's Laboratories is an Indian based pharmaceutical company which imports, markets and sells medicines in South Africa. Dr. Reddy's has plans to set up a manufacturing plant in South Africa, the purpose of this study is to research waste management practices at Dr. Reddy's plant in India and to draw parallels between India's and South Africa's waste legislation. This is to enable Dr. Reddy's to review all aspects of its waste management systems, in order to revise where necessary and to improve the overall achievement of its waste management objectives in order to become a more sustainable organisation and to meet South African Waste legislation before setting up a plant in South Africa.

This research needs to address the gap in analysing waste management practices (with more emphasis on waste treatment, waste minimisation, re-use, recycling and disposal), and implementation and understanding of waste management in the pharmaceutical industry as prior research was done mostly in other chemical industries and not to a large scale in the pharmaceutical industry. South African Waste Legislation, Indian Waste Legislation (as Dr. Reddy's is based in India), as well as International Pharmaceutical Waste Management Guidelines, and International Pharmaceutical Good Manufacturing Practices provide a framework and benchmark of leading pharmaceutical waste management practices that can guide Dr,. Reddy's Laboratories' leadership into integrating their waste management practices into their plans of setting up a manufacturing plant in South Africa.

This section of the research comprises of sub-sections that provides a background to Dr. Reddy's Laboratories in India and its waste management practices. A detailed overview is given to outline each component of Dr. Reddy's waste management strategy. A further sub-section describes as per the literature review, waste definition, types of waste, waste management, waste management strategy implementation and management processes. Also contained within this section of the research are the results of the survey that was conducted at Dr. Reddy's Laboratories in India. The survey was conducted through the utilisation of a questionnaire directed at both factory employees and middle managers who are involved with waste management practices at Dr Reddy's manufacturing facilities in

Hyderabad, India. The questionnaire was compiled using criteria for waste management as outlined in Pharmaceutical Good Manufacturing Practices, Internationally accepted Waste Management Guidelines as well as criteria outlined in South African and Indian Waste Legislation. Survey participants were requested to rate Dr. Reddy's in terms of compliance to the identified criteria and make recommendations that they believed if implemented would improve overall waste management at the company.

1.2 Literature Review

The objective of the literature review is to provide a critical assessment and evaluation of previous research in the field of waste management in general as prior research was done mostly in other industries and not to a large scale in the pharmaceutical industry. The literature review evaluates the key elements of an effective waste management strategy implementation and is followed by a review of literature pertaining to the description of pharmaceutical waste.

The definition of waste in this study is largely based on the definitions given in the *South African White Paper on Integrated Pollution and Waste Management* (2000) which emphasises waste as "any unwanted substance that needs to be discarded".

The literature survey identified various requirements that need to be met in order to develop and implement successful waste management policies and practices in the pharmaceutical industry; these include storage, minimization, recycling, and disposal of pharmaceutical waste. Collection of pharmaceutical waste was however not addressed in the literature reviewed.

The Waste Management Hierarchy was identified in the literature reviewed as the preferred method to manage waste as it favours the minimisation of waste from the point of generation versus the traditional method of waste management which advocates dealing with waste at the end of pipe, usually by disposal to landfill. The Waste Management Hierarchy also favours the re-use and recovery of waste material through recycling, composting of waste energy facilities and only considers landfill as the last resort. However, critics of waste management were also identified in the literature, some of the critics include McDougall and Hruska (2000) who argue that the waste management hierarchy is of limited use as there is no scientific basis

for the way the hierarchy orders waste management treatment options in the way that it does. The criticism of the waste management hierarchy was also pointed out by Rasmussen, Vigso, Ackerman, Porter, Pearce, Dijkgraaf, and Vollengergh (2000) who believe that the waste hierarchy to be a generalised and flexible guideline form of formulating waste policies.

The North Dakota Pharmaceutical Waste Guidance (2010) provides strict guidelines which should be followed in the handling of pharmaceutical waste. The guidelines amongst other things suggest strict labelling of waste containers with hazardous waste and storage of such containers in safe dedicated spaces, the guidelines also advocate that such stored hazardous must be subject to on-going weekly inspections by a suitably qualified waste inspector. Literature review of both Indian and South African legislation also revealed strict controls with regards to the storage of pharmaceutical waste.

With regards to Waste Minimisation, the U.S. Environmental Protection Agency (1991) defines the requirements of Waste Minimisation in the Pharmaceutical Industry. The report states that source reduction of waste can be achieved through changes in products, raw materials, process technologies, or procedural and organisational practices, amongst a list of other things that can be done to minimise waste.

Waste recycling refers to treating waste that is no longer useable in in its present form and using it to produce new products. Rushton (2003: 186) lists the following as advantages of recycling:

- conservation of resources
- supply of raw materials to industry
- reduction of waste disposed to landfill and incineration

However, Rushton (2013) also mentioned critics of waste recycling, this will be mentioned in detail at a later section in this study.

Challenges to managing pharmaceutical waste were also identified. A condensed view of these four performance areas viz storage, minimization, recycling, and disposal of waste involves the definition and identification of different methods for Pharmaceutical Waste Disposal as described by Visvanathan (1996) who states that

hazardous waste disposal methods are available and all necessitate proper pre-treatment, which is carried out with the objective of volume reduction and concentration of wastes, so that waste will be easily disposed of or stored without creating any detrimental effects to the environment; Dijkgraaf and Vollenbergh (2003) state that landfilling is a better option of disposal of hazardous wastes as private costs for incineration are much higher; and Blenkharn (2005) who advises a move away from costly destruction of clinical wastes by incineration; through waste minimization and additional segregation of wastes at source to reduce to a minimum that component of clinical wastes that carries a clear and unquestionable infection risk.

1.3 Research Method

This is evaluation research in the form of a case study and the data collection method employed is the conduction of a survey through questionnaires. The design and content of the qualitative research questions will be informed by methods of management and disposal of pharmaceutical waste from international best practices, and the template would be designed by the researcher and the major components of the questionnaire would be those identified by the Department of Environmental Affairs and Development Planning (2007).

The research method also includes a document analysis of Dr. Reddy's 2012 annual reports, Dr. Reddy's 2010 Sustainability Report as well as reports compiled by the organisation's Corporate Communications Division against Waste Management practices identified through literature review.

1.4 Results

The results are divided into two sections namely results from Dr. Reddy's document analysis and results from the survey conducted at the Dr. Reddy's Manufacturing facilities in India.

1.5 Dr. Reddy's Waste Management Strategy

Dr. Reddy's Senior Management is fully committed to a zero waste generation strategy. The organisation has consciously worked on reducing its carbon footprint for more than a decade now. Management continually seek new and innovative ways of minimising its impact on the environment. These efforts have resulted in declining consumption of finite resources and the use of infinite resources (fresh water and sustainable energy), zero discharge of harmful effluents and responsible disposal of hazardous waste. Dr. Reddy's strategic business partners (third party manufacturers) are also subject to high environmental, safety and quality standards (Dr. Reddy's Laboratories, 2010)

Dr. Reddy's Waste Management Strategy includes the use of resin-based technologies as one innovative way that the organisation has used to reduce solvent usage, solid waste generation and effluent generation. The organisation has made headway in the development of alternate catalysts to replace toxic and unsafe catalysts, thereby improving reaction efficiency and minimising effluent generation (Dr. Reddy's Laboratories, 2010).

1.5.1 Dr Reddy's Waste Management Strategy Implementation

1.5.1.1 Waste Minimisation

Dr. Reddy's quest is to become a 'lean' drug manufacturer. To this end the organisation's two-step strategy has been to drive down the generation of waste during the manufacturing process and then to dispose of waste efficiently. In order to effectively implement both strategies and to achieve significant load-reduction, the company has formed waste minimisation teams at its manufacturing units (Dr. Reddy's Laboratories, 2010). Figure 1 below shows that during the 2009-10 financial year, the total quantity of hazardous waste disposed of was 13,045 tons, a significant reduction of 37% over 2008-09. This decline was on account of a large proportion of hazardous waste being up cycled to cement companies as alternative fuel.

Figure 1: Reduction of Hazardous Waste generated at Dr Reddy's Manufacturing Facilities from 2006 -2010, adapted from Dr Reddy's 2010 Sustainability

Another method that is in use at Dr. Reddy's to minimise generation of waste has been minimising the consumption of solvents, with the remainder produced from the use of reagents and raw materials. High toxicity, low flash points and high vapour pressure in air lead to many of the adverse effects of solvents on environment as well as on human health (Dr. Reddy's Laboratories, 2010).

Dr. Reddy's Sustainability Report, 2010 further mentions that solvents are among the biggest concerns in the pharmaceutical industry and as a result their safe and responsible disposal is Dr. Reddy's foremost priority. The company's primary aim is to minimise the use of solvents through the adoption of green chemistry, a philosophy and study of the design of products or substances that will not involve materials harmful to the environment. The ideal scenario is to virtually stop pollution before it can even begin through the use of non-pollutants and to maximise their reuse through recovery systems.

Dr. Reddy's has substantially reduced use of Class I and Class II solvents. According to Dr. Reddy's 2010 Sustainability Report, Class I solvents include solvents with known human carcinogens, strongly suspected human carcinogens, and those that pose environmental hazards. Class II solvents on the other hand have non-genotoxic animal carcinogens or possible causative agents of other irreversible toxicity such as neurotoxicity or teratogenicity. Dr. Reddy's is particular

that any solvents used in its manufacturing processes are benzene free (Dr. Reddy's Laboratories, 2010).

In one of Dr. Reddy's plants, solvent was procured in barrels and then decanted for usage. This not only led to wastage of solvents through evaporation but also exposed lab personnel to harmful solvent vapours. This situation was proving to be financially expensive, hazardous to personnel health and exposing business to safety and regulatory risks. Dr. Reddy's intervened by developing an innovative closed-looped mechanised solvent handling system. In this system, the solvent is pumped from a tank via a pipe to the product. This process is quick and easy and offers leak free transfer of solvents (Dr. Reddy's Laboratories, 2010).

Not only has Dr. Reddy's managed to minimise the use of solvents as a means towards waste reduction, but wastage of solvent and transfer losses have been virtually eliminated. Environment and personnel hazards during solvent handling have also been eliminated. Usage of barrels has been reduced and along with it the resources needed to treat and clean them before disposal have also been reduced significantly (Dr. Reddy's Laboratories, 2010).

1.5.1.2 Waste Storage at Dr. Reddy's

Waste at Dr. Reddy's is segregated into different categories and these are then treated and stored in different ways as per the Standard Operation Procedure (SOP), relevant SOPs exist for each waste category, (see Appendix B for details of how the different categories are stored), the categories are as follows:

a) Recipient, Treatment & Storage of Hazardous Waste Date Expired, Discarded Off Specification Drugs & Medicines (Hazardous Waste Category-28.3, 28.4)
b) Residues and Waste (Hazardous Waste Category-28.1)
c) Spent Organic Solvent (Hazardous Waste Category-28.5)
d) HDPE Chemical Containers and Liners (Hazardous Waste Category-33.3)
e) Effluent Treatment Plant Sludge (Hazardous Waste Category 34.3)
f) Waste/Used Oil (Hazardous Waste Category-5.1)
g) Other Hazardous Waste
h) Bio-Medical Waste

1.5.1.3 Recycling and Re-use

Recycling and Re-use at Dr. Reddy's include wastewater recycling and solvent recovery. The biggest challenge Dr. Reddy's manufacturing plant had to face was the availability of good quality water in Hyderabad, particularly during the summer months. A solution was found with the commissioning of a state-of-the-art 425KLD waste water recycling facility and commissioning of rain water harvesting. It is expected to improve the water table considerably at the FTO 3 plant and at Bachupally, Hyderabad. The good news is that already about 20 percent reductions in ground water TDS levels have been achieved over the last one year at FTO 3. Other systems implemented included a solvent recovery plant (SRS) for recovering solvents from process exhausts, acoustic enclosures for all the compressors, blowers and major energy conservation projects (Dr. Reddy's Laboratories, 2012).

1.5.1.4 Waste Disposal

The API (Active Pharmaceutical Ingredients) manufacturing process generates high calorific value organic residue, mostly from the solvent distillation process. These wastes were earlier disposed either through site incineration or sent to TSDF for incineration. The opportunity of consumption of high calorific value wastes such as sludge from petrochemical plant; spent solvent residue from pesticide plant in cement industry as alternate fuel was thereby explored (Dr. Reddy's, 2010).

The waste generated at the Dr. Reddy's API plants had a calorific value equivalent to the other waste already used in cement kiln; hence an effort was initiated to look at the possibilities of utilisation as alternate fuel, by co-processing waste residue material as a source of energy, to minimise use of fossil fuels at cement plants (Dr. Reddy's Laboratories, 2010).

Although there were some restrictions and uncertainties in types and quantities of wastes that could be used as fuels in cement plants, this form of disposal was found to be cost effective, with less environmental impact as compared to conventional disposal methods such as land fill and incineration (Dr. Reddy's Laboratories, 2010).

With regards to Hazardous Waste, Dr. Reddy's has Standard Operating Procedure for the disposal of Hazardous waste which amongst other things states the following:

- That detoxified drums & liners be handed over to scrap yard for disposal.
- Waste/Used Oil shall be disposed to authorised recyclers through and agreement.
- Waste/Used batteries shall be handed over to manufacturer/dealer on buy back policy or disposed to CPCB (Central Pollution Control Board) approved recyclers with an agreement as per the Batteries Management & Handling Rules, 2001 of Government of India.
- Bio-Medical Waste shall be disposed periodically to APPCB approved facility as per Biomedical Waste Management & Handling rules, 1998 of Government of India along with manifest copy through an agreement.

1.5.1.5 Conclusion

Upon reflection of Dr. Reddy's waste management practices and strategy, it is evident that Dr. Reddy's has a waste management plan and procedures in place. The waste management processes followed at Dr. Reddy's conform to the processes and legislation defined in the literature review. What is however not evident in all company documents and websites that were reviewed is how the waste management strategy is filtered down and correctly implemented by the organisation's employees, this however does not imply that the objectives of properly managing waste at Dr Reddy's manufacturing facilities were not met, in reality the strategy was well managed and objectives successfully implemented but there is still room for improvement as was ascertained during the survey conducted amongst employees at the manufacturing plant in Hyderabad, India indicating that many do not fully understand waste management processes that are being implemented at the factory.

1.6 Dr. Reddy's Laboratories Survey Results

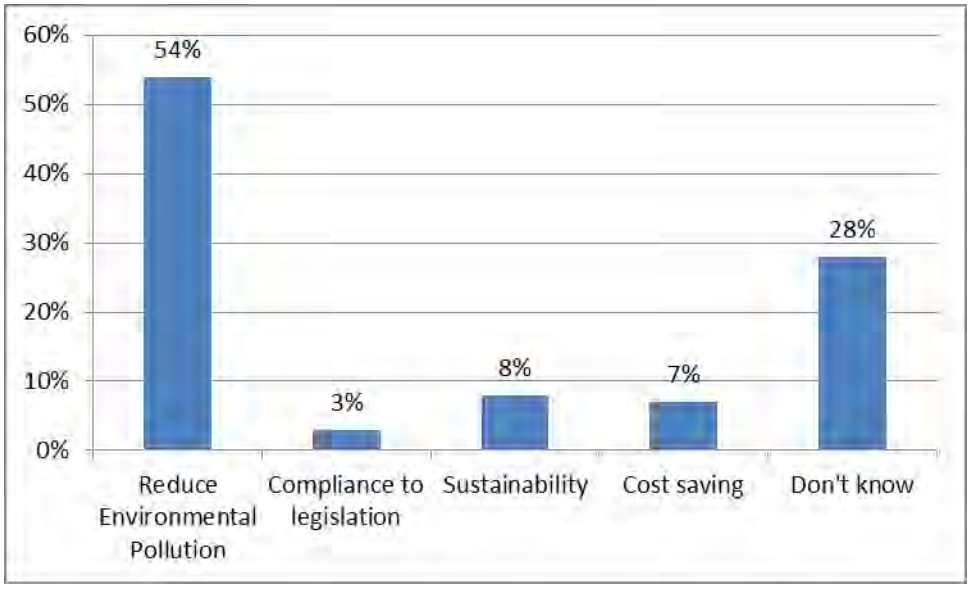
This section presents the consolidated view of the survey conducted to identify Dr Reddy's waste management practices and the understanding of such practices amongst employees. The data was analysed and interpreted following the questionnaire structure, namely:

- A potential reason from employees regarding the need for Dr. Reddy's to have a Waste Management Strategy in place.

- Awareness of Current Waste Management Processes being implemented at Dr. Reddy's.
- Awareness of Indian Waste Legislation regulating the Pharmaceutical Industry.
- The application of Waste Minimisation processes at Dr. Reddy's.
- Implementation of Recycling and Re-use processes at Dr. Reddy's,
- Level of understanding of Waste Management Practices amongst Dr. Reddy's employees.
- Areas of waste management improvement.
- Employee recommendations on how to improve the level of the adoption of waste management practices by fellow employees at Dr. Reddy's.

1.6.1 Reasons from employees Why Dr. Reddy's needs a Waste Management Strategy

The respondents were asked to give their reasons as to why they deemed it important for Dr. Reddy's to have a waste management strategy in place. This is because literature reviewed indicated that employees need to understand the need for a waste strategy for them to buy into it.

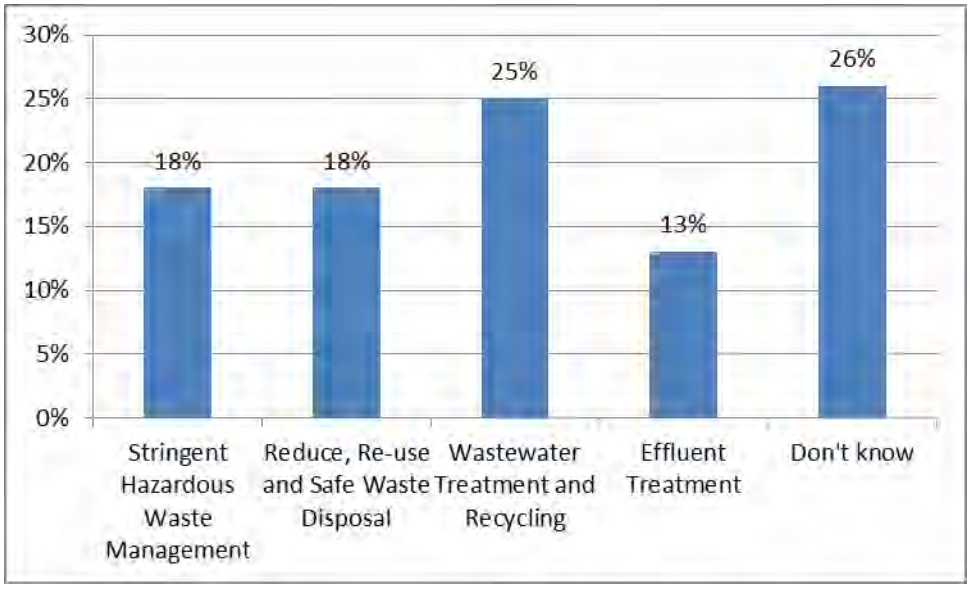


54% of respondents believe that the reason why Dr. Reddy's needs to have a waste management strategy in place is to reduce environmental pollution and protect the environment, this is in line with the company's commitment to protection of the

environment as stated in the organisation's sustainability report. It is however alarming that 28% of respondents do not seem to have a clear understanding as to why the company has a waste strategy in place; these respondents gave reasons ranging from enhancing organisational reputation to simply believing that there is a need for a waste management strategy without stating any apparent reason. 8% and 7% believe the reason Dr. Reddy's has a waste management strategy is to be sustainable and to save on cost, respectively while 3% believe Dr. Reddy's adopted a waste management strategy simply to comply with regulation, all these three reasons have been stated in literature reviewed as some of the benefits of having a waste management strategy in place for corporations.

1.6.2 Awareness of current waste management processes being implemented at Dr. Reddy's

It is important for employees to be aware of current waste management processes being implemented in an organisation in order to adhere to policies and prevent generation of waste.

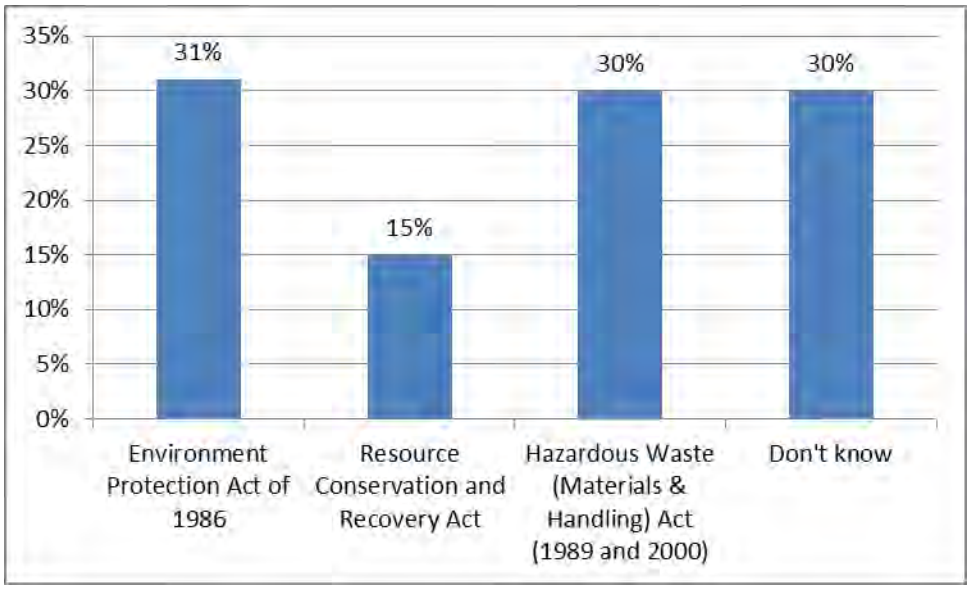


26% of respondents claimed that they did not know what current waste management processes were being implemented, followed by 25% of respondents who indicated that they were aware of wastewater treatment and recycling processes at Dr. Reddy's. Only 18% claim to be aware of stringent Hazardous Waste Management processes at Dr Reddy's despite the organisation showing a significant decrease in Hazardous Waste generation between 2006 and 2010 in its 2010

Sustainability Report. Only 18% and 13% of respondents respectively are aware of efforts by the organisation to reduce, reuse and safely dispose of waste as well as of the treatment of effluent generated at Dr Reddy's manufacturing plant.

1.6.3 Awareness of Indian Legislation regulating the pharmaceutical industry

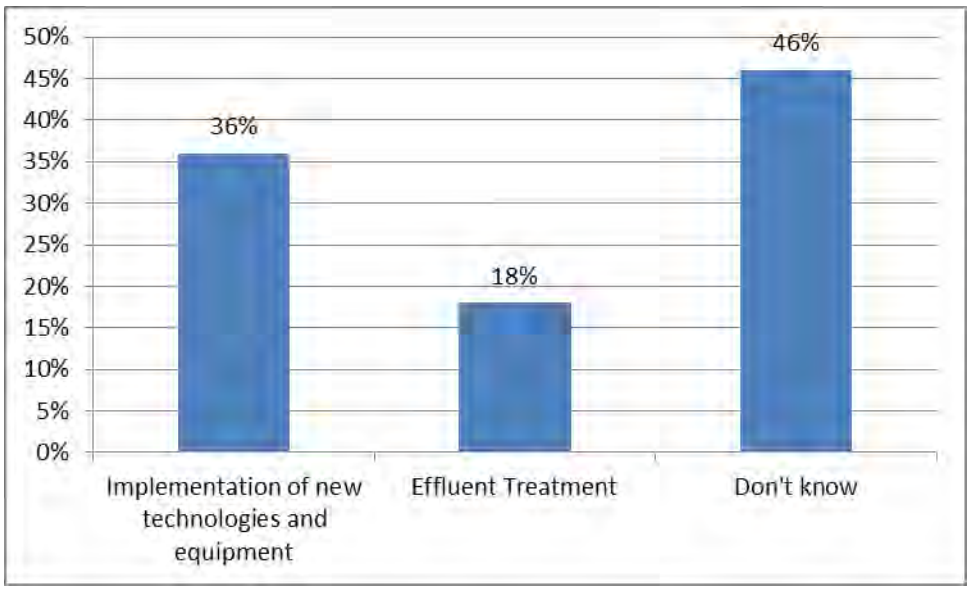
Literature reviewed indicated the importance of legislation in regulating pharmaceutical waste.



Results indicate that 30% of respondents do not know what waste legislation regulates the Indian pharmaceutical company with some respondents suggesting that no waste legislation exists as far as they are aware; some even going to the extent of suggesting that legislation exists only in paper and is not being adhered to in the pharmaceutical industry. Of the other 70% of respondents, 15% are aware of the Resource Conservation and Recovery Act, 30% are aware of the Hazardous Waste (Management & Handling) Act (1989 and 2000), while 31% is aware of the Environment Protection Act of 1986.

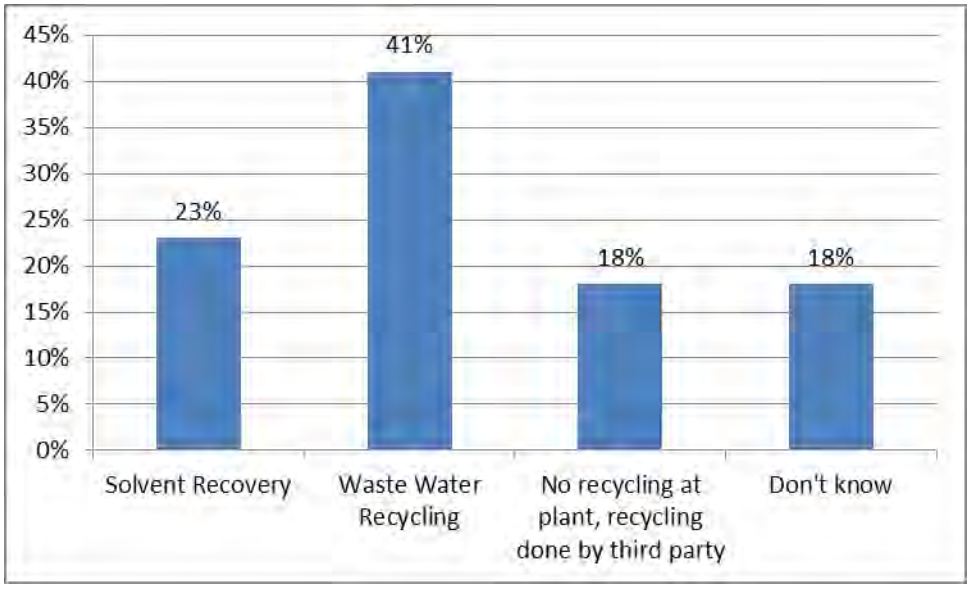
1.6.4 Application of waste minimization processes at Dr Reddy's

It is vital for employees, both those involved with handling waste as well as general shop floor employees to be aware of waste minimisation processes in the organisation in order for them to be able to follow such processes in an effort to minimise the generation of waste in the manufacturing processes.



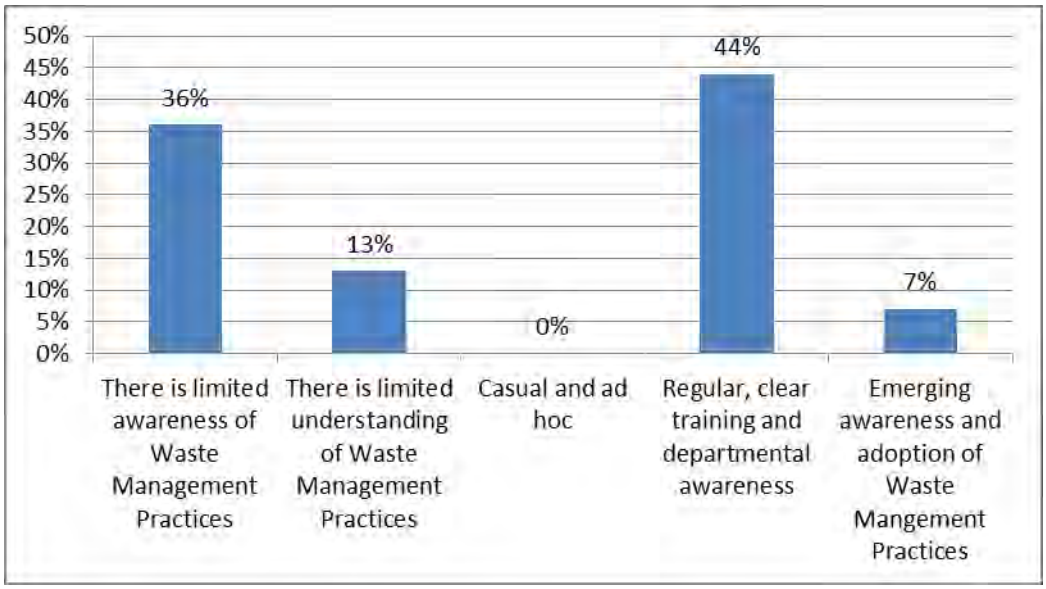
From the results, it is indeed alarming that 46% of respondents do not know what waste minimisation processes are currently in place at Dr. Reddy's. 36% of respondents believe that the implementation of new technologies and the use of automated fast equipment in the manufacturing processes has resulted in significant waste minimisation at Dr. Reddy's, while 18% of respondents believe effluent treatment is practiced in order to minimise waste at Dr. Reddy's. It is evident from the high percentage of respondents that are not aware of waste minimisation processes at Dr. Reddy's that communication regarding these processes should be communicated to employees and management must ensure that there is clarity at all levels of the organisation regarding such processes.

1.6.5 Implementation of Recycling and Re-use processes at Dr. Reddy's



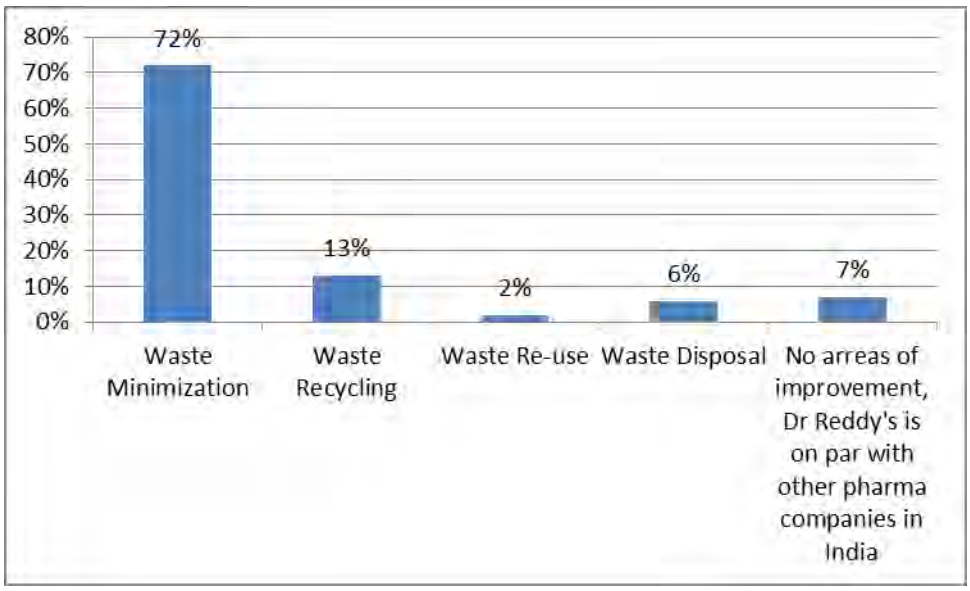
Of those surveyed, 41% indicated their awareness of Wastewater Recycling processes at Dr. Reddy's; this high percentage of respondents does not come as a surprise as Dr. Reddy's has a dedicated waste water treatment plant. 23% of respondents are aware of solvent recovery; this figure should be higher as Dr Reddy's documents indicate solvent recovery a priority for the company. 18% of respondents indicated that they do not know of any waste recycling processes at the company, whereas the other 18% do know of recycling processes but no recycling is done in their plants but recycling of waste from their particular plant is done by a third party. Some of those respondents who were aware of wastewater recycling mentioned wastepaper recycling as a process currently in place at Dr. Reddy's as well.

1.6.6 Level of understanding of Waste Management Practices amongst Dr. Reddy's employees



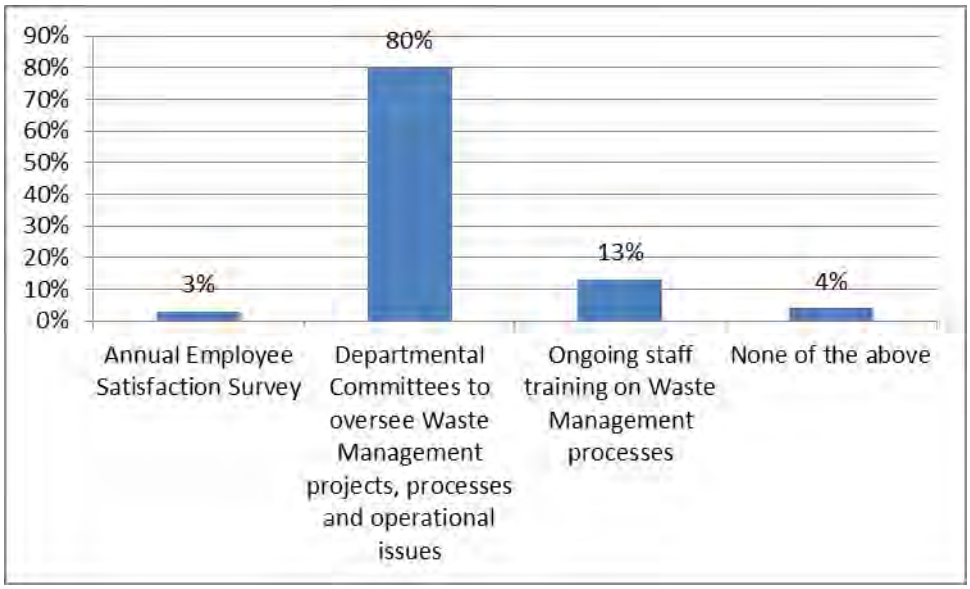
The objective was to have employees analyse their understanding of Waste Management Practices at Dr. Reddy's. Limited awareness of waste management practices means an individual respondent feels they are not aware of the existence of waste management practices at Dr. Reddy's, let alone understand them, 36% of those surveyed said they were not aware of any waste management practices at Dr. Reddy's. 13% of respondents indicated that they were aware of such practices but did not understand them; this could be due to language barrier as some of the workers are not first language English speakers. 44% of the respondents indicated that they have received clear and regular training and that the departments were well aware of waste management practices at Dr. Reddy's and of those respondents none of them thought the training was casual and ad hoc, indicating that they regarded the training as formal and organised. 7% of respondents indicated that there is emerging awareness of the adoption of Waste Management Practices amongst employees at Dr. Reddy's.

1.6.7 Areas of waste management improvement



72% of respondents believe that Dr. Reddy's has to improve its waste minimisation processes, this agrees with the earlier result which indicated that 46% of respondents did not know what minimisation processes were in place at Dr. Reddy's, this indicates that employee training on waste management is needed. Only 13% believe Dr. Reddy's needs to improve on its waste recycling processes, this low percentage indicates that current waste recycling processes are performing well with only slight room for improvement. Only 7% of respondents believe there is no need for Dr. Reddy's to improve on any areas of its waste management and believe that the company is on par with other pharmaceutical companies in India. 2% and 3% of respondents believe that there is a need for Dr. Reddy's to improve on its waste re-use and disposal, respectively.

1.6.8 Employee recommendations on how to improve the level of the adoption of waste management practices by fellow employees at Dr Reddy's



Of the employees surveyed, a significant 80% of respondents would like the company to establish departmental committees to oversee waste management projects, processes and operational issues. 13% would like to have ongoing staff training on waste management, 3% would like the company to conduct employee satisfaction survey to determine the level of satisfaction amongst employees on current waste management practices, while 4% of respondents believe nothing can be done to improve the level of waste management practices by fellow employees.

1.7 Conclusion

This case study while initially undertaken to assess waste management at Dr. Reddy's laboratories has through the survey conducted, revealed gaps in the company's waste management policy implementation created by failure to properly train and educate employees on waste management practices that exist at the organisation. This can guide management's thinking in forming a more intense communication and training strategy to ensure employee adherence to waste management policies and practices.

1.8 Discussion and Recommendations

Results from the survey indicate that Dr Reddy's need to improve certain aspect of its waste management practices as follows:

1.8.1 Waste Management

Company documents that were reviewed indicate that waste management policy exists at Dr. Reddy's but has not been translated into effective procedures as indicated by the lack of awareness of waste management practices by a significant percentage of respondents. This is despite the fact that most of those surveyed directly work with waste handling. Another explanation could be that procedures exist but are not distributed to relevant parties. Waste management policy at Dr Reddy's is based on Indian legal requirements as it is evident in company documents that the company does strictly comply with Indian Waste Legislation. Results of the survey however, indicate that these legal requirements are not properly understood as 30% of employees that were surveyed had no idea what waste legislation regulates the pharmaceutical industry in India. Not being aware of legislation and regulations can lead to non-compliance by employees, which has the potential of straining relations between the organisation and government and the likelihood of fines being imposed on the company for non-compliance.

Rushton (2003) suggested that organisations develop a training programme for employees in an organisation in order to ensure that employees understand and comply with waste management policies and procedures. A recommendation would be made therefore that Dr. Reddy's develop a training programme for all relevant employees at the factory, this type of training should not only be directed at employees who are directly involved with waste handling but all company employees should be trained on the importance of waste management procedures to ensure that waste management is understood and filtered throughout the organisation. To ensure that employees are constantly aware of waste management procedures and policies, management should communicate waste management successes to staff, senior managers, and stakeholders outside the organisation with an interest in waste management.

1.8.2 Waste Storage

Dr. Reddy's has Standard Operating Procedures with regard to waste storage. These Standard Operating Procedures is deeply entrenched in legislation that regulates the management of Hazardous waste in India. Review of Indian and South African Waste Legislation has revealed a number of similarities between the two countries legislation pertaining to storage of waste, where very stringent regulations are in place for storage of hazardous waste. However, South African Waste Legislation goes into much more detail than Indian Waste Legislation, with more regulations in place for storage of hazardous waste. The recommendation would be that Dr. Reddy's senior management should familiarise themselves with South African Waste Legislation prior to establishing a manufacturing plant in South Africa, the organisation would be required by law to obtain a licence from the South African Minister of Environmental Affairs and Tourism granting them permission to handle waste and would be required to submit a waste management plan before such a licence can be granted. Various rules and regulations apply to waste storage in India and each is under the jurisdiction of specific authorities, the same applies in South Africa, which then means that Dr. Reddy's would have to familiarise itself with the relevant authorities responsible for granting permission for the storage, handling and transportation of hazardous waste.

1.8.3 Waste Minimisation

From the results it is clear that Dr. Reddy's is committed to waste minimisation through implementation of new technologies and the use of automated and improved equipment as indicated by 36% or respondents. However, 46% of respondents were not aware of any minimisation processes that are in place. Based on the research findings, the recommendation is that Dr. Reddy's conduct a survey to determine the level of understanding of minimisation processes amongst its employees and address this through measures such as training and visible posters in work various work stations throughout the manufacturing plant, outlining in easy to understand language minimisation processes that need to be adhered to. Management also needs to provide easy access to information and technical guidance to employees.

1.8.4 Waste Recycling and Re-use

The findings indicate that there is a relatively good understanding of waste recycling processes amongst staff at Dr. Reddy's, only 18% of respondents did not know of recycling practices at Dr. Reddy's. This could be those employees not directly involved with the handling of industrial pharmaceutical waste, but should however be aware of the importance of recycling, not only of waste but of recycling of other recyclable material such as waste paper recycling.

1.8.5 Understanding of Waste Management amongst employees

The findings suggest that Dr. Reddy's does conduct regular and clear training to increase departmental awareness on waste management practices, but this training clearly has not succeeded in increasing levels of understanding on waste management practices among employees as there is still a high percentage of employees that do not understand or are aware of waste management practices at Dr. Reddy's. It is recommended therefore that Dr. Reddy's ensure that each employee is evaluated after training to ensure common and proper understanding of what practices need to be followed if they are currently not doing this.

1.8.6 Areas of waste management improvement

The findings indicate recommendations from the employees at Dr. Reddy's on what waste management practices need to be improved at the organisation. 72% of employees strongly believe that the company needs to improve on its waste minimisation processes; the recommendation is that management need to heed this call as it clearly shows that employees do not have an understanding of the company's waste minimisation efforts, which carries the risk of non-compliance. Suggestions to address this include workshopping ideas with employees on waste minimisation processes they would like to see in place and measure the feasibility of such.

1.9 Case Study Conclusion

The overall findings of this case study suggest that although management at Dr. Reddy's are satisfied with waste management practices and results achieved at it manufacturing plant, there is however dissatisfaction amongst employees who believe the organisation has not successfully disseminated information and sufficiently trained them on waste management policies, processes and practices. There is therefore a desire amongst employees to be trained and to see the company improve on its waste management processes, this desire is a very important attribute as it indicates that employees at Dr. Reddy understand and are committed to the importance of waste management.

On the legislation front, it is commendable that Dr. Reddy's strive to adhere to Indian Waste legislation, however, literature reviewed does not indicate the existence of any stringent measures to ensure that non-compliance to legislation is punishable in India. South African waste legislation seems to be more prudent in communicating clearly its punitive measures on non-compliance. Dr Reddy's would therefore need to engage a third party, preferably a legal expert to assist with the analysis of South Africa's waste legislation versus Indian waste legislation to ensure clear understanding of local legislation prior to establishing a manufacturing facility in South Africa. Areas of future research include determining in detail the financial benefits that a pharmaceutical company could gain by incorporating integrated waste management in its corporate strategy.

1.10 References

BABBIE, E., 2008. *The Basics of Social Reseach* (4ed). Belmont, CA: Thompson Wordsworth.

BERRY, M.A., RONDINELLI, D.A., 2000. Environmental Management in the Pharmaceutical Industry: Integrating Corporate Responsibility and Business Strategy. *Environ. Qual. Mange.*9:21-25

BLENKHARN, J.I., 2005. *Safe Disposal and effective destruction of clinical wastes.* 18 South Road, Ealing, London W5 4RY, UK.

DEAP, 2007. (Department of Environmental Affairs and Development Planning) *Status Quo of Waste Management in the Consumer-Formulated Chemical Sector of the Western Cape.* Pretoria: Department of Environmental Affairs and Development Planning.

DJIKGRAAF, E., VOLLENBERGH, R.J., 2003. Burn or Bury? A social Cost Comparison of Final Waste Disposal Methods. Erasmus University, Rotterdam and OCFEB, Rotterdam.

DR REDDY'S LABORATORIES, 2010. *Sustainability Report 2010* [Online]. Available: http://www.drreddys.com/aboutus/sustainability.html. [Accessed: 30 May 2012].

DR REDDY'S LABORATORIES, 2010. *Molecules Memories and Moments: A Dr Reddy's Presentation,* July 2010.Dr Reddy's Corporate Communications, Hyderabad, India.

DR REDDY'S LABORATORIES, 2012. *Annual Report 2012* [Online]. Available: http://www.drreddys.com/investors/pdf/annual [Accessed: 18 June 2012].

GUBA, E.G., LINCOLN, Y.S., 1994. Competing Paradigms in Qualitative Research. In Denzin, N.K. and Lincoln, Y.S. (5ed). *Handbook of Qualitative Research*.

MC DOUGALL, F.R., HRUSKA, J.P., 2000. "Report: the use of life cycle inventory tools to support an integrated approach to Solid Waste Management". *Waste Management Res, 18:590-594.*

NGWULUKA, N.C., OCHEKPE, N.A., ODUMOSU, P.O., 2011. An assessment of pharmaceutical waste management in some Nigerian Pharmaceutical Industries. *African Journal of Biotechnology*, 10, 54: 11259-11268, 19 September, 2011.

North Dakota's Pharmaceutical Waste Guidance 2010 [Online]. Available: http://www.ndhealth.gov/wm/Publications/NorthDakotaPharmaceuticalWasteGuidance.pdf [Accessed: 19 June 2012]

ORLIWOSKI, W.J., BAROUDI, J., 1991. Studying information technology in organizations: Research Approaches and Assumptions. *Information Systems Research,* 2,1: 1-28.

RASMUSSEN, C., VIGSO, D., ACKERMAN, F., PORTER, R., PEARCE, D., DIJKGRAAF, E., VOLLENGERGH, H., 2005. Rethinking the Waste Management Hierarchy. Environmental Assessment Institute, Copenhagen.

REMENYI, D., WILLIAMS, B., 1996. "Some aspects of ethics and research into the Silicon Brain.", *International Journal of Information Management,* 16,6: 401-411.

RUSHTON, L., 2003. Health hazards and waste management. *British Medical Bulletin,* 68:183-187.

SEADON, J.K., 2010. Integrated Waste Management, Doctor of Philosophy Thesis, The University of Auckland, and Auckland, New Zealand.

VISVANATHAN, C., 1996. Hazardous Waste Disposal. Environmental Engineering Program. Asian Institute of Technology. Bangkok, Thailand.

WEYBRECHT, G, 2010, The Sustainable MBA: The Managers Guide to Green Business, West Sussex, England: John Wiley & Sons Ltd.

2 Section 2: Literature Review

The section introduces the research area, provides the objectives of the research, provides contextual background information and describes the rationale for conducting the research. This section further describes Dr. Reddy's waste management practice as outlined in relevant company documentation and presents the results of the survey conducted amongst Dr. Reddy's employees.

2.1 Introduction

One system that an organisation should adopt to minimise the impact of its activities on the environment is that of waste management. In order to establish and implement successful waste management policies, it is imperative to understand what constitute waste. Defining material as "waste" has an impact on what measures can be taken with it, and also what restrictions on its transport, sale and reuse can be applied. According to the European Council's Directive on Waste, waste is "any substance or object which the holder discards or is required to discard" (Staniskis, 2005: 40). This definition of waste may become a barrier to an efficient and sustainable management system. "Sustainable waste management calls for resource conservation measures, which in turn requires that attention is given to more than just existing waste. Waste management should entail control of processes that generate waste, waste handling, and waste utilization." (Staniskis, 2005: 45).

The objective of this literature review is to provide a critical assessment and evaluation of previous research in the field of waste management. This literature review evaluates the key elements of an effective waste management process and implementation and is followed by a review of literature pertaining to pharmaceutical waste management and legislation pertaining to pharmaceutical waste.

In the context of the aforementioned the research case study is to establish the implementation and success of waste management practices and policies at Dr. Reddy's Laboratories. The research is intended to address and highlight any issues with regards to waste management that need to be improved at Dr. Reddy's manufacturing facilities in Hyderabad, India before the organisation could expand its manufacturing facilities to South Africa.

2.2 Literature Review- Waste Management

2.2.1 Introduction

According to Envirowise, a government funded programme that offers free and valuable environmental advice to businesses in the UK, "The true cost of waste is not simply the cost of discarded materials - it encompasses inefficient use of raw

materials, unnecessary use of energy and water, faulty products, waste disposal of by-products, waste treatment and waste labour. The actual cost of such waste for UK companies is typically 4-5% of turnover, and can be as high as 10%." Effective management of waste should therefore be part of every organisation's Environmental Management System. Waste management does not only allow organisations to minimise the impact of their activities on the environment but it also allows them to reduce costs by making processes more efficient and by minimising or eliminating waste. This chapter provides an introduction to the key concepts required for waste management. The chapter further explores the foundational attributes of the pharmaceutical waste management process required for effective waste management.

2.2.2 Definition of Waste

In the South African *White Paper on Integrated Pollution and Waste Management (2000)*, waste is defined as: "[An] undesirable or superfluous by-product, emission, or residue of any process or activity which has been discarded, accumulated or been stored for the purpose of discharging or processing. It may be gaseous, liquid or solid or any combination thereof and may originate from a residential, commercial or industrial area. This definition includes industrial wastewater, sewage, radioactive substances, mining, metallurgical and power generation waste."

The *White Paper on Integrated Pollution and Waste Management (2000)* further argues that there is ongoing debate as to the exact definition of waste as a result of an increasing global trend to reduce, re-use, rework, recycle, recover, what is termed "waste" products. This is further complicated by the fact that one man's waste can be another man's valuable raw material. A general definition of waste could therefore be redefined as "something that nobody wants at a particular moment in time and that needs to be disposed of". Waste can be classified into hazardous waste, a broad term for a wide range of substances that may have variable degrees of risk. This includes for instance, toxic substances that may cause cancer. The three largest waste streams in the hazardous waste category are oils and oily wastes, construction and demolition waste and asbestos, and waste from organic chemical processes. Other types of waste which do not pose the same level of risk, such as certain types of household waste are classified as non-hazardous waste.

2.2.3 Definition of Waste Management

Waste management refers to the collection, transport, processing, disposal, managing and monitoring of waste materials. Waste management usually relates to materials produced by human activity, and the process is generally undertaken to reduce their effect mainly on health and the environment. Waste materials can be solid, liquid, gaseous or radioactive and all these different forms fall within the realm of waste management. The priority in which wastes should be managed is demonstrated below in the waste hierarchy (Figure1) as promoted in most international companies' waste management strategies.

Waste management hierarchy	
Cleaner production	Avoidance
	Minimisation and reduction
Recycling and processing	Re-use
	Recovery
	Composting
Treatment	Physical
	Chemical
	Destruction
Disposal	Landfill

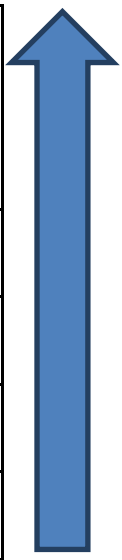


Figure 2: The waste management hierarchy requires moving waste management from disposal to landfill to preferred options higher in the hierarchy

The hierarchy stresses the need to firstly reduce the amount of waste created, then re-use the wastes, then recover (via recycling, composting or waste-to-energy facilities) and finally, as a last resort to dispose the waste to landfill. Whereas the traditional method of waste management deals with waste at the end of the pipe, once it is produced, usually by disposal to landfill, waste hierarchy on the other hand maintains that the most successful means to manage waste is not to produce it in the first place and this is the driving force behind the idea of waste minimisation.

Critics of the waste hierarchy believe it is not the best form of waste management, McDougall and Hruska (2000) argue that there is increasing awareness that the waste management hierarchy which ranks treatment options in a descending order of desirability, is of limited use. The authors argue that no scientific basis exists for ordering waste management treatment options in this way. McDougall and Hruska (2000) believe that the hierarchy cannot provide any guidance with respect to using combinations of treatment technologies. They further believe that the waste management hierarchy does not, and cannot, address cost issues and will not identify the best practical environmental option with respect to planning waste management systems.

This criticism of the waste hierarchy is shared by Rasmussen, Vigso, Ackerman, Porter, Pearce, Dijkgraaf, and Vollengergh (2005) who argue that the waste hierarchy must be considered a very generalised and flexible guideline form of formulating waste policies. The authors emphasise that what is environmentally desirable is not always the solution when viewed from a socio-economic perspective and that some environmental benefits may come at a comparably socially high cost. Rasmussen *et al.* (2005) further share the opinion that marginal costs and benefits will vary depending on material and locality. Their recommendation is that social costs and benefits of new recycled schemes be analysed first and a critical assessment be made to determine if further steps are in fact socially desirable.

2.2.4 Waste Avoidance/Minimisation

Waste avoidance refers to the prevention of waste generation or the reduction of generated wastes. According to the Gwydir Shire Council - Waste Management Plan 2012, examples of practices for achieving waste avoidance include:

- input substitution
- increased efficiency in the use of raw materials, energy, water or land
- process redesign
- product redesign
- improved maintenance and operation of equipment
- closed-loop recycling

The UK based Chartered Institute of Purchasing and Supply believes that for any organisation to take action to reduce waste, it must take its high level plan and turn it into an action plan, this requires the organisation to start by identifying obvious areas of waste reduction where immediate and substantial savings can be achieved by implementing no-cost and low-cost measures. A Waste Minimisation Assessment Procedure as shown below should be adopted by every organisation:

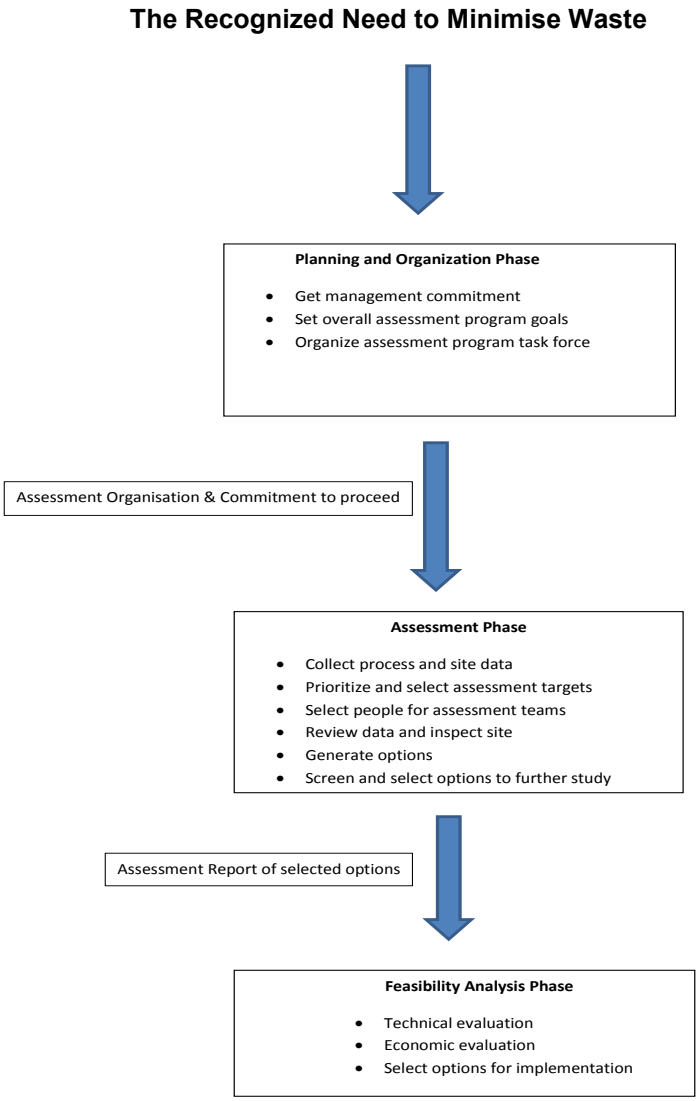


Figure 3 The Waste Minimisation Assessment Procedure, Adapted from the U.S. Environmental Protection Agency.

According to the Chartered Institution of Waste Management and The Waste Framework Directive of 1991 (91/156/EEC), there can be a distinction between:

i) Qualitative waste prevention and reduction

It includes the use of less toxic or hazardous resources and the production of less toxic or hazardous wastes. This is particularly interesting for the chemical industry as several of the reactant substances are hazardous and often toxic and their substitution might have an effect on the qualities of the product.

ii) Quantitative waste prevention and reduction

It includes the use of less resources and the production of less waste in terms of waste per unit of products. That is, it sets as a target the maximum possible minimization of waste per product used. (Kefala and Romano, 2006: 14)

Companies that seek to improve their environmental performance can do so by either using control or clean technologies (Murphy and Gouldson, 2000: 36). The former are end-of-pipe technologies that are used to treat any waste after it has been produced. Cleaner production according to Zhi-dong, Zhang, Zhang, Zhang, and Wei (2011: 195) is an effective way to reduce waste emission and save resources, and has been widely employed in the pharmaceutical industry in developed countries. According to the U.S. Environmental Protection Agency Report (1991) waste minimisation in the pharmaceutical industry involves the following:

- Source reduction of hazardous waste which can be achieved through changes in products, raw materials, process technologies, or procedural and organisational practices.
- Material substitution in the form of a change in one or more of the raw material used in production in order to reduce the volume of toxicity of waste generated.
- Process modification by looking for source reduction opportunities that can be accomplished through modification or modernisation of the existing process, for example, automated systems for material handling and transfer, such as conveyor belts for bagged materials, can help reduce spillage.

Waste reduction is the key to reducing the growing waste mountain, and thus the key to sustainable waste management. Reducing the thickness of plastic bags is a method of reducing waste quantities by reduction in the amount of packaging (Williams, 2005)

2.2.5 Waste Re-use

If waste cannot be reduced then waste re-use is the next priority. Re-use can be defined as *"using a product or package more than once or re-using it in another application"* (Williams, 2005: 129).

The Gwydir Shire Council – Waste Management plan 2012 describes Waste re-use as re-using waste, without first substantially changing its form. Examples of waste re-use are:

- recovering solvents, metals, oil, or components or contaminants from catalysts and re-using them for a secondary purpose
- applying waste to land in a way that gives agricultural and ecological benefits
- substituting waste for virgin material in a production process

2.2.6 Waste Recycling

Waste recycling refers to treating waste that is no longer useable in in its present form and using it to produce new products. Rushton (2003: 186) lists the following as advantages of recycling:

- conservation of resources
- supply of raw materials to industry
- reduction of waste disposed to landfill and incineration

Composting is another form of waste recycling; this is an aerobic, biological process of degradation of biodegradable organic matter. Rushton (2003) argues that composting has the advantage of reducing waste to dispose to landfill and incineration and that composting leads to recovery of useful organic matter for use of as soil amendment. However, Rushton (2003) also criticizes composting by pointing the following of its disadvantages:

- Composting leads to the production of Bio-aerosols which is organic dust containing bacterial and fungal spores which may be harmful to humans.

- Composting emits volatile organic compounds.
- Composting is a potential pathway for contaminants to enter the food chain.
- Composting is associated with bad odours, noise, and vermin nuisance.

Critics of waste recycling argue that recycling has a number of disadvantages; this view is supported by Rushton (2003: 13) who states the following as disadvantages of waste recycling:

- diverse range of processes
- emissions from recycling process
- may be more energy used for processes than original manufacture
- currently low demand for products
- requires co-operation from individuals

2.2.7 Waste Treatment and Disposal

Rushton (2003) has identified incineration and landfilling as two methods of waste treatment and disposal. Incineration as a method of waste treatment is defined as a process of combustion designed to recover energy and reduce the volume of waste going to disposal. Rushton (2003: 184) defines landfill as " the deposition of waste in a specially designated area, which in modern sites consists of a pre-constructed 'cell' lined with an impermeable layer (man-made or natural) with controls to minimize emissions."

Advantages of incineration as a method of waste treatment have been identified by Dijkgraaf and Herman (2003: 2) as the following:

- Incineration waste to energy facilities not only reduce final disposal of waste, but also produce electricity and/or heat, saving (energy) resources elsewhere.
- Burning waste in waste incineration plants facilitates compliance with the Kyoto Protocol.

However, Dijkgraaf and Herman (2003: 2) also identified disadvantages associated with incineration as the following:

- Incineration plants also contribute to externalities such as emission to air and chemical waste residues.

- Incineration plants are expensive to build compared to even modern landfills.

Taiwo (2011:95) also pointed out the following two disadvantages of incineration: construction and start-up costs of facilities, which could be too expensive for developing countries, as well as acid gases production.

Landfilling as a form of waste disposal has been shown in literature review as still the dominating method of waste disposal. Rushton (2003: 184) listed the following amongst advantages of landfilling:

- cheap disposal method
- waste used to back fill quarries before reclamation
- landfill gas contributes to renewable energy supply

Dijkgraaf and Herman (2003: 2) concurred with these advantages but not only identified advantages of landfilling but also criticised this method of waste disposal by pointing out the following disadvantages associated with the method:

- methane production, however Dijkgraaf and Herman(2003) further argue that methane can be a source of energy.
- most landfills do not recover energy.
- odour, dust , road traffic problems
- leaking is often a serious problem, especially for older landfill sites.

2.2.8 Conclusion

In review of the aforementioned waste management processes it can be noted that waste management is an important phenomenon that enables an organisation to be sustainable and reduce the impact of its activities on the environment and on human health. This view is supported by Kefala and Romano (2004: 16) by stating that there have been several positive and encouraging results observed of business that have had financial benefits as a consequence of the introduction of a "'greener policy'.

Within them, businesses have created sustainability development policies and waste management is one of them. As others have argued (Bebbington and Gray, 2001: 560), at the moment there is a debate as to whether the business community could fulfil the sustainability requirements.

2.3 Literature Review – Pharmaceutical Waste

2.3.1 Introduction

According to ToxicsWatch Alliance, an Indian based organisation that keeps track of callousness, corporate crimes, military-mining industrial complex and their impact on humans and ecosystem, "Pharmaceuticals form a group of substances that are of considerable importance for society as healthcare tools. Given the fact that a variety of pharmaceuticals can now be detected in surface, ground, and drinking waters, there are valid concerns about the potentially adverse environmental consequences of this contamination. The risk is directly proportional to the active concentration of the chemical substance in various environmental compartments, and pharmaceutical waste adds to that risk if not managed properly." (ToxicWatch Alliance against Pollution & Corporate Crimes, 2009: 1). Naturally, there is growing concern that human health and aquatic life may be severely impacted as a result of exposure to pharmaceutical compounds. Key concepts covered in the literature reviewed include definition of waste (pharmaceutical hazardous waste in particular), waste management, waste storage, waste minimization, recycling, waste disposal as well as legislation pertaining to waste management.

2.3.2 Definition

Pharmaceutical waste is defined according to ToxicWatch Alliance as “a pharmaceutical that is a hazardous waste.” Sources of pharmaceutical waste include excreted substances, improper disposal by hospitals and patients, agricultural waste due to veterinary use and livestock feed additives (Zuccato *et al*., 2000; Heberer, 2000, cited in Ngwuluka *et al.*, 2011). This research will only focus on pharmaceutical waste in the context of the pharmaceutical manufacturing industry.

2.3.3 Hazardous waste

The National Environmental Management: Waste

Act 59 of 2008, (Waste Act) of South Africa defines Hazardous Waste as “any waste that contains organic or inorganic elements or compounds that may, owing to the inherent physical, chemical or toxicological characteristics of that waste, have a detrimental impact on health and the environment”. Sharma, Dilip, Khilip, Gupta, and Bisht (2010: 333) give a more detailed definition of hazardous waste by defining a characteristic hazardous waste as a waste that has been identified to exhibit one or more of the following attributes:

1. Ignitable:

A. Flash point is less than 140 degrees Fahrenheit (e.g. solutions containing more than 24% alcohol).

B. An oxidiser.

C. An ignitable compressed gas as defined by the U.S. Department of Transportation (e.g. some aerosol propellants).

2. Corrosive:

A. The pH is less than or equal to 2.0 or greater than or equal to 12.5.

B. It is a liquid and corrodes steel at a rate greater than six and thirty-five hundredths millimetres per year (e.g. compounding chemicals, including strong acids, such as glacial acetic acid, and strong bases, such as sodium hydroxide).

3. Reactive:

A. Reacts violently with water.

B. It is normally unstable and readily undergoes violent change without detonating.

C. It forms potentially explosive mixtures with water.

D. When mixed with water, it generates toxic gases, vapour or fumes in a quantity sufficient to present danger to human health.

4. Toxic: Fails to the Toxicity Characteristic Leaching Procedure (TCLP) (e.g. contains arsenic, barium, cadmium, chloroform, chromium, lindane, m-cresol, mercury, selenium or silver at a concentration equal to or greater than the regulatory level).

See fig.1 below for a summarised definition of classes of hazardous waste.

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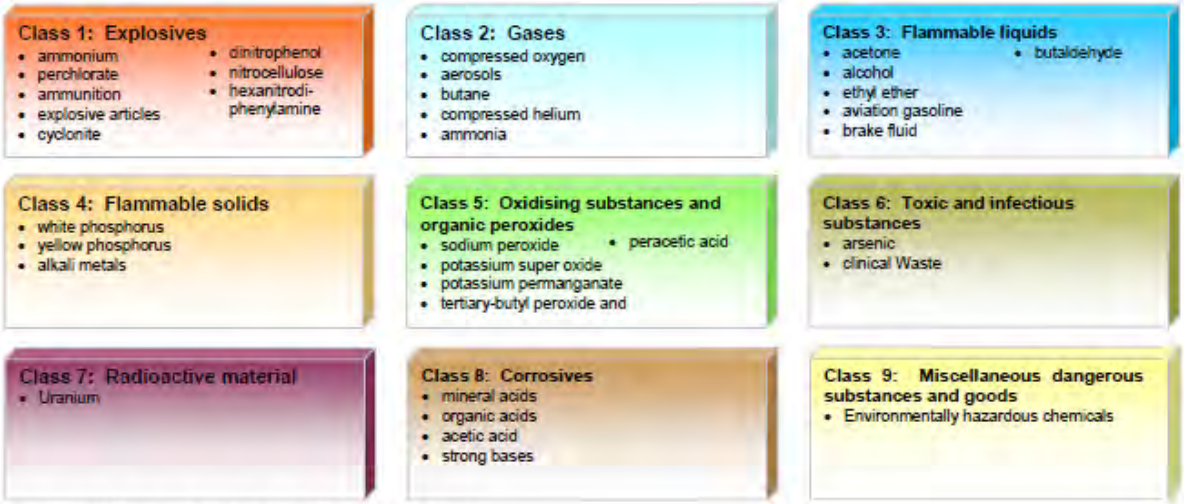
The table below further gives examples of waste generated per class:



Source: SANS 10228 and various others from Reference List

Table 1: Examples of Types of Waste per Waste Class

2.3.4 Types of Pharmaceutical Waste

According to the U.S. Environmental Protection Agency Guidelines to Pollution Prevention, the Pharmaceutical Industry (1991), "Pharmaceutical manufacturing plants generate a variety of wastes during manufacturing, maintenance and housekeeping operations. Typical waste streams include spent fermentation broths, process liquors, solvents, equipment wash waters, spilled materials, off-spec products, and used processing aids". Pharmaceutical waste may be present in any of the common physical forms like solids, liquids and gases. The waste can be categorized in several ways, e.g., depending on source, physical state, hazard, security, handling and disposal (ToxicWatch Alliance against Pollution & Corporate Crimes, 2009:2). Andreassen and Fletcher (1993) identified three main sectors that contribute to the generation of waste in the pharmaceutical industry, these are:

Research and Development where generally everything that enters a R&D site leaves as waste but the main form of waste produced is paper due to the considerable amount of paper used which includes drug registration documents, trials data, process details etc.

Primary manufacturing where there is considerable use of organic solvents in synthetic work and the vast use of water in fermentation processes. The main sources of waste from a facility are liquids and solids, in that order.

Secondary Manufacturing is probably the least wasteful of the three sectors. Andreassen and Fletcher (1993) identified water as the first waste from this sector and packaging material as another main waste from the secondary sector.

Pharmaceutical waste includes expired, unused, spilt and contaminated pharmaceutical products, drugs, vaccines and discarded items as bottles, vials, connecting tubing (Samakhanova, 2006: 7). In the case of Dr Reddy's, this study is more concerned with waste generated during the manufacturing process.

Other types of pharmaceutical waste identified in literature review include halogenated/non-halogenated solvents, sludge & tars, heavy metals, organic chemical residues from still bottom, test animal remains, return pharmaceuticals, low-level radioactive waste, contaminated filters, etc.

2.3.5 Pharmaceutical Waste Management

Andreassen and Fletcher (1993) argue that the first necessary step to take after making a company commitment to improving waste management is to establish what the current situation is at the working level, the authors suggest that a waste audit be undertaken for this reason; such an audit is typically comprised of:

- A review of the waste management structure
- An inspection of the generation, handling and disposal of waste
- An assessment of compliance with existing legislation
- An assessment of the implications of forthcoming legislation.

Andreassen and Fletcher (1993) suggest that result of such audits should be listed and discussed under the following sections:

- Waste Management
- Waste Storage
- Waste Generation/Disposal
- Waste Minimization

This view of waste management is supported by Townsend and Cheeseman (2005, cited in Ngwuluka *et al.*, 2011) , who propose that management of waste involves

waste segregation, waste collection, waste transportation, waste storage, waste disposal, waste minimization and reuse. I concur with Ngwuluka et al (2011) who further mention that waste management requires the five pillars of management - planning organising, leading, co-ordinating and monitoring for efficacy and effectiveness. Incorporating the five pillars of management I believe is essential in ensuring that waste management is considered an important part of general management by senior management in any pharmaceutical company.

2.3.6 Waste Management

Andreassen and Fletcher (1993: 63) identified various scenarios that can exist with regards to waste management in the pharmaceutical industry, these are:

- Policy statements exist, but have not been translated into effective procedures.
- Procedures exist, but do not set out the requirements clearly or designate responsibility for actions.
- A timetable for producing and implementing the procedures is non-existent or incomplete.
- Procedures exist, but are not distributed.
- Little or no training towards procedures is undertaken.
- Procedures are based on legal requirements of other countries and are not directly applicable or understandable locally.

Andreassen and Fletcher (1993) argue the importance of having work procedures relating to waste management in an organisation and of passing information on working methods in a written format as opposed to passing such information verbally to employees. The authors also emphasise the importance of having a central figure responsible for waste management to ensure co-ordination of waste management activities throughout the organisation. Both these views are supported by the U.S. Pharmaceutical Waste Management Guidelines which an organisation should appoint a Hazardous Waste Program Manager and/or Environmental Manager who shall:

- Develop a training program for all relevant personnel within the Environmental Programs Division, Pharmacy Department, and Nursing Department on handling and disposing of hazardous waste;
- Develop an inspection program to ensure compliance with state and federal hazardous waste regulations;
- Conduct a re-evaluation of the hazardous waste generator status of the activity based on the addition of hazardous pharmaceutical waste to the generated waste stream;
- Develop new Standard Operating Procedures (SOPs) to ensure implementation of waste guidelines;
- Integrate the new SOPs into the Environmental Management System (EMS); and
- Modify other existing SOPs as necessary to implement the necessary guidelines.

I agree with the above mentioned which is also supported by the U.S. Chartered Institute of Purchasing and Supply (2007: 18) which listed top 10 Tips for managing wastes and developing waste strategies for companies, these are:

1. Understand the legal implications of the waste produced in your organisation by identifying the specific legislation that affects you.
2. Look at your general environmental issues - what role does your waste play in these?
3. Quantify and identify your waste. Where does it arise and how much does it cost? Undertake a walk around audit and look at your bills. Using the waste hierarchy, identify what currently happens to the waste as it arises.
4. Identify a waste management champion or team to drive things forward.
5. Produce an action plan for reducing your wastes.
6. Get commitment from senior management for the action plan.
7. Identify the possible disposal options where you cannot reduce or recycle.
8. Select your waste carriers carefully and make sure your Duty of Care responsibilities are met.
9. Monitor and review your achievements.

10. Communicate your successes to your staff, senior managers, and outside your organisation to interested stakeholders.

Andreassen and Fletcher (1993) warn against the existence of a number of company sites with little coordination which may then lead to inconsistent approaches to waste management, where various standards and practices may arise. This undesirable situation will then make it difficult to adopt common waste management procedures but can also provide an interesting selection of approaches from which the best can be chosen to form the basis of any new universal procedure.

2.3.7 Waste Storage

The North Dakota Pharmaceutical Waste Guidance provides general guidelines that should be followed in the handling of hazardous pharmaceutical waste. The guidelines suggest that waste be separated and stored by waste classification, P- or U-listed, toxicity, ignitability, corrosivity or reactivity. The North Dakota Pharmaceutical Waste Guidance (2010: 8) suggests that while containers of hazardous pharmaceutical waste are in storage:

- Each container must be labelled “hazardous waste’.
- Each container must be clearly marked with an “accumulation start date”. The accumulation start date is the date that waste is first placed (accumulated) in the container.
- Each container must be closed unless adding or removing waste.
- The storage area must maintain adequate aisle space for inspections and emergency responses.
- The containers in storage must be inspected weekly, and inspection log must be kept.

The importance of proper waste storage is further emphasised by Andreassen and Fletcher (1993) who argue that uncovered, unsegregated, unbounded, unlocked storage areas for hazardous waste, as well as poor labelling of drummed waste are some of the improper waste management storage activities that do occur in pharmaceutical manufacturing plants. Andreassen and Fletcher (1993: 63) further argue that “Adequate labelling of waste may only take place prior to transportation off –site. Thus, in the event of an emergency situation or spillage on-site, personnel

may have little idea as to the nature of the contents and therefore of the optimal actions to be taken". Andreassen and Fletcher (1993: 63) therefore emphasise that "comprehensive labels, detailing the hazardous characteristics and constituents of the waste, should be placed on the waste containers as soon as possible". In my opinion, labelling of waste containers may not entirely achieve the desired purpose in a factory like Dr Reddy's where the majority of factory workers are illiterate.

2.3.8 Waste Generation / Disposal

The study conducted by Ngwuluka *et al.* (2011: 11261) looking at the assessment of pharmaceutical waste management in some Nigerian pharmaceutical industries revealed the following regarding the generation of pharmaceutical waste and wastewater:

- Most of the respondents could not ascertain the quantity of waste generated. Other respondents did not understand that it was necessary to know the quantity of waste generated as it would determine the method of disposal.

- All manufacturing pharmaceutical industries generated wastewater, which resulted from the water used for process operations during manufacturing and in contact with intermediary, finished and/or by-products. Wastewater could come from the water used to clean equipment, pipes and floors, and would contain amongst other materials, chemicals and active pharmaceutical ingredients. Ngwuluka *et al.* (2011: 11262) also revealed how pharmaceutical waste is disposed of. First, an industry would write stating the drugs or raw material to be disposed with quantities. A staff member would go to assess the waste, container, the chemical content and the quantity, and a sample would then be taken for analysis to identify a suitable solvent that will dissolve the waste. Ngwuluka *et al.* (2011: 11262) further explain that the identified solvent and pharmaceutical waste is mixed in a mixing tank, transferred into the diluting tank where pH is adjusted to neutral and diluted with water before the liquid is flushed into the environment.

With regards to disposal of solid wastes generated during pharmaceutical manufacturing, Ngwuluka *et al.* (2011: 11263) identified open air burning as an unfavourable method of waste disposal as it generates toxic emissions into the air.

Pharmaceutical waste should be burnt in well-constructed incinerators at recommended temperatures with means of controlling emissions.

According to Upadhyay *et al.* (2005: 264), landfill is the most common method for disposal of wastes in most countries. As landfill is associated with continuous and long term operation, it is necessary to plan for effective solid waste management to achieve maximum reduction of wastes for disposal and landfill. Upadhyay (2005) further argues that incineration is the commonly used process to reduce the quantum of solid wastes. Incineration refers to the controlled burning of wastes at high temperature (500-1200 C) in a furnace especially designed for this purpose and the products of incineration are ashes and gases. I am more inclined to agree with Upadhyay *et al* (2005) who go on to criticise landfilling as a method of disposal as they argue that land availability , pollution of water and sail are some of the main problems faced in landfill disposal, however, these problems can be minimized if the landfill area is scientifically designed, compacted and clay lined before dumping of wastes. Upadhyay *et al.* (2005) suggest that the hazardous wastes could be treated properly through physical/chemical/biological methods before being dumped in landfill areas or disposed of in containers in the underground/ocean.

Mathew and Unnikrishnan (2012) mention that industrial effluents in India are handled by end-of-pipe treatment, which like common effluent treatment plans, results in residual persistent organic pollutants and toxic metals in the treated water.

2.3.9 Waste Minimisation

According to Andreassen and Fletcher (1993: 66) once waste generation has been detailed, targets should be set for waste minimization. 'Target' areas should be placed in a priority list where top of the list is areas where maximum reductions in waste generation can be obtained by the minimum degree of effort. There are various means that the pharmaceutical industry can adopt to minimise waste including Green Chemistry, according to Mathew and Unnikrishnan (2012: 33) "Green chemistry minimises by-product waste and replaces the worst reactions with green technology. Many routine chemical reactions in pharma manufacturing can be replaced with green but expensive alternatives." This view is supported by Sharma N *et al.* (2010: 333) who states that "the pharmaceutical industry has made progress over the past several years in practicing "green chemistry", for example by

minimizing use of reagents that are hazardous to the environment and by designing alternate synthesis pathways".

Other measures to minimize waste in pharmaceutical manufacturing were identified by the U.S. Multilateral Investment Guarantee Agency and include the following:

- Meter and control the quantities of active ingredients to minimise wastage.
- Reuse by-products from the process as raw materials or as raw material substitutes in other processes.
- Recover solvents used in the process by distillation or other methods.
- Give preference to the use of non-halogenated solvents.
- Use automated filling to minimize spillage.
- Use "closed" feed systems into batch reactors.
- Use equipment wash-down waters and other process waters (such as leakages and pump seals) as make-up solutions for subsequent batches.
- Recirculate cooling water.
- Use dedicated dust collectors to recycle recovered materials.
- Vent equipment through vapour recovery systems.
- Use loss free vacuum pumps.
- Return toxic materials packaging to the supplier for reuse or incinerate/destroy in an environmentally acceptable manner.
- Minimize storage time of off-specification products through regular reprocessing.
- Find productive uses for off-specification products to avoid disposal problems
- Minimize raw material and product inventory to avoid degradation and wastage.
- Use high pressure hoses for equipment cleaning to reduce wastewater.
- Provide storm water drainage and avoid its contamination from process areas.
- Label and store toxic and hazardous materials in secure bounded areas. Spillage should be collected and re-used.

2.3.10 Conclusion

This section highlighted the scenario of waste management in the pharmaceutical manufacturing sector and the options available for the management, storage,

generation and disposal, as well as minimization of such waste. The literature reviewed indicated that the Pharmaceutical Industry generates various kinds of wastes of biodegradable and non- biodegradable categories. The impact of such waste on the environment is enormous, if not properly managed and disposed of. Some pharmaceutical waste can be recycled, such as solvents, and the industry can also minimise the generation of wastes and exercise proper collection and disposal technologies of waste that already exists.

2.4 Literature Review – Waste Legislation

2.4.1 Introduction

Environmental legislation is a relatively young approach to waste and pollution control, with most environmental legislation having been passed in the past 20-30 years in developed countries, and even more recently in developing countries (Goodstein,2002, cited in Godfrey and Nahman,2007). Godfrey and Nahman (2007: 1) argue that while regulatory controls have historically been the dominant approach to controlling pollution in developed and developing countries, a shift in governance away from 'policing' to one of co-operation has seen the introduction in developed countries of a number of 'softer' alternative, policy instruments. In developing countries, regulatory control remains the principle means of waste and pollution control; however, failures in compliance and in the enforcement of waste legislation have generally resulted in deterioration in the management of waste (Sterner, 2003 cited in Godfrey and Nahman, 2007). Oelofse and Godfrey (2008: 245) mention the importance of the definition of waste to the regulation of waste and the control of possible negative impacts of waste on the environment and human health if not properly manages. Oelofse and Godfrey (2008) thus conclude that waste should be defined in a way that will support the regulation of the environmental impacts and support the principles of integrated waste management as outlined in the waste hierarchy.

2.4.2 Indian Waste Legislation

The Indian pharmaceutical industry produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies as well as formulations in various dosage forms. Indian exports are destined to more than 200

countries around the globe including highly regulated markets of US, Europe, Japan and Australia (Government of India Department of Pharmaceuticals, 2010). The Government of India Department of Pharmaceuticals 2010 Report also states that the pharmaceutical industry is regulated by a number of acts and rules, viz. the Water (Prevention and Control of Pollution) Act of 1974, the Air (Prevention and Control of Pollution) Act of 1981, the Environment Protection Act of 1974, the Manufacture, Storage and Import of Hazardous Chemicals Rules of 1989, the Chemical Accidents (Emergency Planning, Preparedness, And Response) Rules of 1996, the Disaster Management Act of 2005, the Public Liability Insurance Act of 1991, the Factories Act of 1948 etc. The Report further states that the industry is prone to environmental regulatory / legislation risks due to the emission of pollutants including toxic emissions and odour, effluents that are not easily biodegradable and toxic in nature, hazardous wastes that are in the form of liquids, solids, gases or sludges and hazards due to handling, transportation and storage of hazardous chemicals including warehouses, godowns, tank forms in ports/fuel depots docks.

The Indian government promulgated the Environment (Protection) Act in 1986, which is the umbrella legislation to protect and improve the environment and to regulate the management and handling of hazardous substances and chemicals (Khanna , Kumar, and Kulkarni., 2010: 1). The authors further argue that experience in India shows that most industries respond to environmental issues by complying with government regulations, but if corporations do take an antagonistic position towards regulations, they continue to be burdened with ever-increasing regulations and adverse judicial pronouncements. According to Khanna *et al.* (2010: 2) hazardous waste in India has been defined as “any substance, excluding domestic and radioactive waste, which because of its quantity and/or corrosive, reactive, ignitable, toxic and infectious characteristics causes significant harm to human health or environment when improperly treated, stored, transported and disposed”. Khanna *et al.* (2010: 2) state that in India, a comprehensive legislative framework has been in place for over ten years to address issues related to hazardous waste management but there is still a significant backlog when it comes to the implementation front.

Khanna *et al.* (2010: 3) explain that the Environment (Protection) Act of 1986 prohibits the emission or discharge of environmental pollutants in excess of

prescribed standards, and it also sets mandatory procedural safeguards for handling hazardous substances. It has accorded wide-ranging powers to the national government to take all measures deemed necessary for protecting or improving the environment. These powers include:

- Laying down standards for emissions and discharges to maintain environmental quality;
- Restricting the siting of industries;
- Defining safeguards to prevent industrial accidents and concomitant remedial measures;
- Laying down standards for hazardous waste management, hazardous chemical transport and handling, and the import and export of hazardous wastes and chemicals;
- Inspection of polluting sources and direction to prevent, control and monitor pollution;
- Information collection and dissemination on pollution in the country in addition to the governmental efforts to control pollution.

Lastly, the rules framed by the Indian government for hazardous waste management under the Environmental (Protection) Act of 1986 are:

- Hazardous Waste (Management and Handling) Rules, 1989 (January 2000 amendment)
- Manufacture, Storage and Import of Hazardous Chemicals Rules,1989
- Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Chemicals and Genetically Engineered Organisms or Cells, 1989.

2.4.3 Hazardous Waste (Management and Handling) Rules (1989 and 2000)

The Hazardous Waste (Management and Handling) Rules of 1989 provide for the control of generation, collection, treatment, transport, import, storage and disposal of wastes listed in the schedule annexed to these rules. The State Pollution Control Boards (SPCBs) and the state governments implement these rules, which are applicable to 18 categories of waste. In order to be subject to regulation, however, the rules set a threshold amount of hazardous waste in each category. No regulation applies at levels below the threshold. (Khanna *et al.*, 2010: 4). Khanna *et*

al. (2010) further elaborate that the responsibility for identification of sites for common treatment, storage and disposal facilities and individual toxic substance disposal facilities is assigned not merely to the state government, but also to the industrial associations responsible for the waste generation.

The responsibilities of various authorities involved in the implementation of the Hazardous Waste Rules are summarised below.

Sr. No.	Activity	Authority			
		MoEF	SG	SPCB	CPCB
1	Survey & inventorisation of HW generators and processors			X	
2	Grant authorisation for handling HW to units of operators			X	
3.	Inspect facilities/infrastructures/technical Capabilities in HW handling units.			X	
4.	Suspend/refuse/cancel authorisation for handling HW			X	
5.	Identify and notify sites for HW treatment /disposal facilities		X	X	
6.	Facilities EIA studies before identifying sites		X	X	
7.	Collect, collate and publish list of abandoned HW dump sites		X		
8.	Establish a system for filing of annual returns, and reporting of accidents by the HW units and operators			X	

9.	Process and grant permits for import of HW to units			X	
10.	Examine and permit/refuse exporters request for HW import to India.	X			
11.	Issue instructions to importers of HW	X			
12.	Inform port authorities to take appropriate steps for safe handling at ports	X		X	
13.	Inspect records of imports	X		X	X
14.	Process appeals		X		

MoEF: Ministry of Environment and Forests; SPCB: State Pollution Control Board; SG: State Government; CPCB: Central Pollution Control Board.

Table 2: Responsibilities of Authorities in India for the Implementation of Hazardous Waste Rules.

2.4.4 Manufacture, Storage and Import of Hazardous Chemical Rules, 1989

According to Khanna *et al.* (2010: 5) these rules have been formulated to address the issues involved in manufacturing, storing and importing industrial hazardous chemicals. The rules specify that the occupier of the land on which hazardous substances will be handled is obliged to provide evidence that the major accident hazards have been identified and adequate steps have been taken to prevent such accidents and to limit their consequences to humans and the environment if they do occur. Khanna *et al.* (2010) further mention that the occupier is requested by law to provide information, training, personal protective equipment and emergency medicine to ensure the safety of employees working within industrial premises. The rules also specify strict quantities of each chemical that can be stored and request that these are reported to authorities, the authorities in turn have the duty to inspect and ask for the report on chemical being handled and on the storage details thereof.

Indian waste legislation as identified in literature is very prescriptive but does not clearly define what punitive measures are in place for failure to adhere to the

legislation as laid out by the government. My deduction is that the laws are just procedural with no strict enforcement in place.

2.4.5 South African Waste Legislation

To analyse current waste management practices and legislation governing waste management practices in South Africa and recommendations for improvement, the following literature was reviewed: Waste Management Practices (DEADP, 2007) which identify waste minimisation in terms of source reduction and recycling as important in waste management planning and argues that although basic measures are in place for waste management, there is still room for improvement; Environment Conservation Act 73 of 1989; National Environmental Management: Waste Act 59 of 2008. The National Environmental Management: Waste Act 59 of 2008 supersedes all waste legislation in South Africa. According to the Waste Act 59 of 2008, waste generated during pharmaceutical manufacturing is defined as health care risk waste and the act has various rules and regulations pertaining to the segregation, packaging, labelling, and storing of such waste which the pharmaceutical industry has to stringently adhere to as follows according to the Government Gazette published on 1 June 2012.

2.4.5.1 Segregation

1) The Waste Act 59 of 2008 states that health care risk waste must be segregated and containerised at the point of generation.

2) Containers must be colours coded in accordance with SANS 10248-1 (as amended).

2.4.5.2 Packaging

1) No health care risk waste must leave a generator unless contained in rigid, leak proof and puncture resistant containers.

2) Any health care risk waste must be packaged in accordance with SANS 10248-1 (as amended).

3) Packaging for health care risk waste shall be filled to no more than three-quarters capacity of the container.

4) All sharps waste must be packaged in sharps containers manufactured in accordance with SANS 452 (as amended).

5) Plastic bags used as an interim storage container supported in a rigid frame must be in accordance with SANS 10248-1 (as amended).

6) Plastic bags used as liners which form an integral part of a rigid container must be in accordance with SANS-10248-1 (as amended).

7) All plastic bags used for the packaging of health care risk waste must be managed as health care risk waste and must not be reused.

8) All plastic bags shall be closed by means of non-PVC plastic ties, non-PVC plastics sealing tags of the self-locking types or heat sealers purpose-made for health care risk waste.

9) Anatomical waste not suitable for containerisation must be double bagged sealed and placed in a single-use container.

10) Isolation waste must be double bagged, sealed and placed in a single-use container.

11) Reusable containers, excluding sanitary waste bins, must be cleaned and decontaminated after each use in accordance with set standards as they appear in the annexure usually found attached to the regulations.

2.4.5.3 Labelling

1) All health care risk waste containers excluding interim storage containers must be sealed and labelled, bar coded or micro chipped to reflect the following:

a) the date container is sealed

b) the generator's registration number issued in terms of Waste Information Regulations,2011 for major generator, or

c) that the waste is from a minor generator.

2.4.5.4 Storage

Health care risk waste must be stored in designated area that-

a) is inaccessible to unauthorised personnel and members of the public;
b) is secured by means of suitable locks;
c) is under cover and protected against the elements;
d) is appropriately ventilated;

e) has adequate pest control measures;
f) has access to running water and is linked to a sewer;
g) is capable of storing clean and dirty containers separately;
h) is clearly signposted with warning signs as to the nature of the health care waste being stored; and
i) is clearly signposted with the contact details of the person in charge of the designated area.

The Waste Act 58 of 2008 requires generators, transporters and waste managers to be in possession of relevant licensing allowing them to hold, transport and manages health care risk waste.

2.4.6 Conclusion

This section introduced the role and importance of legislation in pharmaceutical waste management. Literature reviewed introduced various rules and regulations pertaining to waste management that are in place both in India and South Africa. The review of literature pertaining to Indian waste legislation was more extensive as the subject of the research is manufacturing plant based in India. South African waste legislation, although more recent than Indian waste legislation in comparison seems to be more prescriptive, especially with regards to storage of health care risk waste and the law is very clear regarding punitive measures for non-adherence.

2.4.7 Literature Review References

ANDREASSEN, L., FLETCHER, N.A., 1993. Pharmaceutical Waste Handling and Disposal, *Pharmaceutical Engineering Manufacturing International,* 1993 edition.

BEBBINGTON, J., GRAY, R., 2001. An account of sustainability: Failure, success and a reconceptualization, *Critical Perspectives of Accounting* 12:221-244.

CHARTERED INSTITUTE OF PURCHASING & SUPPLY, 2007.*How to develop a waste management and disposal strategy.* [Online]. Available: http://www.cips.org. [Accessed 17 November 2012].

DEAP, 2007. (Department of Environmental Affairs and Development Planning). *Status Quo of Waste Management in Consumer-Formulated Chemical Sector of the Western Cape.* Pretoria: Department of Environmental Affairs and Development Planning.

DEAT (2000). White Paper of Integrated Pollution and Waste Management for South Africa. DEAT, Pretoria [Online]. Available: http://www.gov.za/gazette/whitepaper/2000/20978.pdf [Accessed: 12 July 2012].

DIJKGRAAF, E., VOLLENBERGH, H.R.J., 2003.Burn or Bury? A social cost comparison of final waste disposal methods. Erasmus University, Rotterdam.

Environmental Protection Agency Guidelines to Pollution Prevention, the Pharmaceutical Industry (1991) [Online]. Available:http://www.ndhealth.gov/wm/Publications/NorthDakotaPharmaceuticalWasteGuidance.pdf [Accessed: 9 September 2012]

Gwydir Shire Council- Waste Management Plan 2012.

KEFALA, A., ROMANO, C., 2006. Waste Management in large Corporations: reality vs. rhetoric.

KHANNA, P., KUMAR, R., KULKARNI, V., 2010. Case study 3: Hazardous Waste Issues in India [Online]. Available: http://www.eolss.net/Sample-Chapters/C09/E1-08-06.pdf [Accessed: 4 September 2012].

MATHEW, G., UNNIKRISHNAN, M.K., 2012. The Emerging Environmental Burden from Pharmaceuticals. *Economic & Political Weekly.* Vol XIVII. No.18.

MC DOUGALL, F.R., HRUSKA, J.P., 2000. "Report: the use of life cycle inventory tools to support an integrated approach to Solid Waste Management". *Waste Management Res, 18:590-594.*

MURPHY, J., GOULDSON, A. 2000. Environmental policy and industrial innovation: integrating environment and economy through ecological modernisation. *Geoform,* 31:33-44.

National Environmental Management: Waste Act 59 of 2008.

NGWULUKA, N.C., OCHEKPE, N.A., ODUMOSU, P, O., 2011. An assessment of pharmaceutical waste management in some Nigerian pharmaceutical industries. *African Journal of Biotechnology,* 10, 54:11259-11268.

North Dakota's Pharmaceutical Waste Guidance 2010 [Online]. Available: http://www.ndhealth.gov/wm/Publications/NorthDakotaPharmaceuticalWasteGuidance.pdf [Accessed: 19 June 2012]

OELOFSE, S.H.H., GODFREY, L., 2008. Defining waste in South Africa: Moving beyond the age of 'waste'. *South African Journal of Science* 104.

RASMUSSEN, C., VIGSO, D., ACKERMAN, F., PORTER, R., PEARCE, D., DIJKGRAAF, E., VOLLENGERGH, H., 2005. Rethinking the Waste Management Hierarchy. Environmental Assessment Institute, Copenhagen.

RUSHTON, L., 2003. Health hazards and waste management. *British Medical Bulletin,* 68:183-187.

SAMAKHANOVA, A., 2006. Drivers and barriers for healthcare waste minimization in Kaliningrad. *Thesis for the fulfilment of the Master of Science in Environmental Management and Policy.* Lund University, Sweden.

SHARMA, N., DILIP, A., KHINCHI, M., GUPTA, M.K., BISHT, S., 2010. Pharmaceutical Waste Management: A challenge to make Environment eco-friendly. *International Journal of Research in Ayurveda & Pharmacy,* 1, 2:332-338.

STANISKIS, J., 2005. Integrated Waste Management: Concept and Implementation. *Environmental Research, engineering and management*, 3, 33:40-46.

The Chartered Institute of Purchasing & Supply. *How to develop a waste management and disposal strategy. Top 10 tips for Managing Your Wastes* [Online]. Available: http://www/cips.org [Accessed: 3 September 2012].

TOWNSEND, W.K., CHEESEMAN, C.R., 2005. Guidelines for the evaluation and assessment of the sustainable use of resources and of waste management at healthcare facilities. *Waste Manage. Res,* 23, 5:398-408.

ToxicsWatch - Alliance Against Pollution & Corporate Crimes [Online]. Available: http://toxicswatch.blogspot.com/2009/01/notes-on-pharmaceutical-waste.html [Accessed: 29 August 2012].

U.S. ENVIRONMENTAL PROTECTION AGENCY,1991. *Guide to Pollution Prevention, The Pharmaceutical Industry.* Ohio: Centre for Environmental Research Information, Office of Research and Development.

UPADHYAY, V.P., PRASAD, M.R., SRIVASTAV, A., SINGH, K., 2005. Eco Tools for Urban Waste Management in India. *J.Hum. Ecol,* 18, 4:253-269.

Waste ACT 59, 2008. *Government Gazette* Vol564, No.35405. 1 June 2012.

WILLIAMS, P., 2005. *Waste Treatment and Disposal* (2nd ed). Chichester, John Wiley & Sons.

ZHI-DONG, L., ZHANG, S., ZHANG, Y., 2011. Evaluation of cleaner production audit in pharmaceutical production industry: Case Study of the pharmaceutical plant in Dalian, P.R. China. *Clean Tech Environ Policy,* 13: 195-206.

3 Section 3: Description of Research Methodology

This section describes the research methodology undertaken during the research case study. This includes the context and objectives of the research, assessment tool, data management and ethical considerations.

3.1 Introduction

This section presents a description of how the work in this research was conducted. This is an evaluation report presented in the form of a case study which is intended to describe, understand and evaluate rather than predict and explain (Remenyi & Williams, 1996). This section presents the research process followed in compiling this case study, represented by the aims and objectives, research methodology and design, and data collection techniques.

3.2 Context of Research

The DEAT (2000) White Paper on Integrated Pollution and Waste Management for South Africa realised the importance of introducing Integrated Pollution and Waste Management by adopting a paradigm shift from dealing with waste only after it is generated towards pollution prevention, waste minimisation, cross-media integration, institutional integration, both horizontal and vertical, of departments and spheres. In the Draft Health Care Risk Waste Management Policy (DEAT, 2008) pharmaceutical manufacturers and pharmacies have been identified amongst generators of waste and as a result are bound to the policy which deals with healthcare risk waste, its management and the treatment thereof. Although this research is on Dr. Reddy's waste management at the factory in India, it will be conducted with both Indian and South African Waste legislation in mind to make recommendations to Dr. Reddy's on which legislation needs to be upheld in order to successfully run a manufacturing plant in South Africa.

3.3 Objectives of the Research

According to Welman, Kruger, and Mitchel (2011: 193), "In hypothesis-testing research we deal with the general and the regular deduction. In case studies, on the other hand, we are directed towards understanding the uniqueness and the idiosyncrasy of a particular case in all its complexity". Thus the aim of this research is to describe the concepts and theory of Waste Management and Pharmaceutical Waste Management in particular and determine whether waste management policies and practices at Dr. Reddy's Laboratories adhere to these concepts and theories

. Secondly, through the utilisation of legislative criteria and Pharmaceutical Good Manufacturing Practice, assess compliance of waste management practices at Dr. Reddy's.

3.4 Methodology

The general research approach of this study is a qualitative one. The data obtained from the literature review has been used as a guideline for a more comprehensive perspective on specific waste management practices and policies at Dr Reddy's.

The research questions focus on how Dr Reddy's has dealt with waste management issues and whether the way it has dealt with these issues has been effective according to their employees, or whether there is need to improve on these issues. The research method employed is Evaluation Research with a document analysis of Dr Reddy's 2012 annual report, 2010 sustainability report and corporate literature against waste management processes and practices identified through literature reviewed. A questionnaire was also used to sample the data needed in this study on which employees rated the extent to which they are satisfied and understand various aspects of waste management practices and policies at Dr Reddy's.

3.5 Population and Sample Size

Of the total population of more than 1000 employees at Dr. Reddy's Manufacturing facilities at Hyderabad, India, only 100 employees were sampled for this research. The sample was selected using stratified random sampling and included from the lowest level of employees to middle managers within the factory. The sample was selected to exclude those who were illiterate and could not read, write or understand English. All those selected had a minimum education of grade 12, and middle managers had a tertiary qualification. All the employees in the sample were proficient in English and were either directly or indirectly involved with waste management at the factory.

3.6 Data Collection Techniques

The data collection was performed in two phases. The first phase was literature research performed over a period of time. This stage was mainly exploratory in order to obtain an in depth understanding of waste management issues. The second stage was the conduction of a survey through distribution of survey questionnaires.

One hundred questionnaires were distributed to individuals, 50 questionnaires were distributed to those who work directly with waste management including control/assurance managers, regulatory officers, superintendent pharmacists, and environmental officers. The other 50 questionnaires were distributed to randomly selected factory employees who are not directly involved with waste management in order to assess their understanding of waste management processes at Dr. Reddy's. The random sampling method that was used was stratified random sampling to include only employees with a good understanding of the English language as a large percentage of employees at the factory are illiterate and have difficulty understanding English. In total a response rate of 61% was realised with 61 of the 100 questionnaires being returned for the purpose of the analysis. Of the 61 questionnaires, the majority were from those directly involved with waste management (43) and 18 were from general factory employees not involved with waste management. The theory that was discussed in the literature review section provided the framework for the data required from the questionnaire

The design and content of the research questions were informed by theoretical methods of management of pharmaceutical waste as determined through review of literature and by criteria set in Waste Legislation of both South Africa and India.

The survey questionnaires were drawn up from previous research reviewed in literature review including waste management criteria set by Department of Environmental Affairs and Development Planning (2007) in South Africa.

The detailed questionnaire is in Appendix A.

3.7 Data Analysis

The informative data collected during the interview sessions was utilised to create the background and detail narrative to understand pharmaceutical waste management processes that were implemented and followed at Dr. Reddy's manufacturing facilities in Hyderabad, India.

The survey incorporated questions from each of the four main areas of waste management viz. Waste Minimization, Waste Recycling, Waste Re-use, and Waste Disposal. The data obtained following administration of the questionnaires was

presented in the simple percentage of the numbers that responded to each interview question.

3.8 Ethical Considerations

Permission has been granted by Dr. Reddy's Laboratories Head Office in India to the researcher to carry out the research and conduct aforementioned interviews. The researcher is in the employ of Dr. Reddy's Laboratories as a Product Manager, thus the researcher was from the onset aware of concerns relating to subjectivity, confidentiality, and bias. The principles underlying 'research ethics' are universal and concern issues such as honesty and respect for the rights of the individuals (Welman *et al.*, 2005).

According to Welman *et al.* (2005), ethical considerations come into play at three stages of the research project, namely:

- When the participants are recruited.
- During intervention and/or the measurement procedure to which they are subjected.
- In the release of the results obtained.

In lieu of the above and to avoid unethical practices, the researcher used as a guideline Bassey's (1999) three principles of ethical practice drawn from case study research which ensured effective governance and ethical behaviour through the research:

Respect for persons: This ensured that respondents understood the questions, the rationale to partake in the research, and the right to privacy.

Respect for democracy: Each respondent was explained the role and type of the research conducted and was given the opportunity to withdraw from the study, as well as assured confidentiality at all times.

Respect for truth: The researcher ensured that the research was conducted, examined and reported with rigour and depth to ensure validity of the findings.

3.9 Conclusion

According to the interview and survey participants, research of this nature has never been undertaken at Dr Reddy's Laboratories. The result and ensuring recommendations will create awareness of what needs to be improved in terms of waste management policies and practices as the organisation moves forward and expands its manufacturing facilities into South Africa. The results of the survey data are presented and commented on to provide an overall assessment of waste management practices based on criteria set by Waste Management Legislation and Pharmaceutical Waste Management Guidelines.

3.10 References

BABBIE, E., 2008. *The Basics of Social Research (4e).*Belmont, CA: Thompson Wardsworth.

BASSEY, M., 1999. *Case study research in educational settings.* Buckingham: Open University Press.

DEAT, 2000. (Department of Environmental Affairs and Tourism). *White Paper on Integrated Pollution and Waste Management for South Africa, A policy on Pollution Prevention, Waste Minimization, Impact Management and Remediation.* Government Gazette, 17 March 2000.

DEAT, 2008. (Department of Environmental Affairs and Tourism). *White Paper on Integrated Pollution and Waste Management for South Africa.* Pretoria: Department of Environmental Affairs and Tourism.

DEAP, 2007. (Department of Environmental Affairs and Development Planning). *Status Quo of Waste Management in the Consumer-Formulated Chemical Sector of the Western Cape.* Pretoria: Department of Environmental Affairs and Development Planning.

GODFREY, L. and NAHMAN, A., 2007. *Are developing countries ready for first world waste policy instruments?* Eleventh International Waste Management and Landfill Symposium, Oct. Italy: Environmental Sanitary Engineering Centre.

GOVERNMENT OF INDIA DEPARTMENT OF PHARMACEUTICALS, 2010. *Annual Report 2010.* [Online]. Available: http://pharmaceuticals.gov.in/annualreport2010. [Accessed 19 November 2012].

GUBA, E.G., LINCOLN, Y.S., 1994. Competing Research Paradigms in Qualitative Research. In Denzin, N.K, Lincoln, Y.S. (ed). *Handbook of Qualitative Research.* London: Sage Publications.

ORLIKOWSKI, W.J., BAROUDI.J., 1991. Studying information technology in organizations: Research approaches and Assumptions. *Information Systems Research,* 2, 1: 1-28.

REMENYI, D., WILLIAMS, B., 1996. “Some Aspects of ethics and research into the Silicon Brain.”, *International Journal of Information Management,* 16,6: 401-411.

TAIWO, A.M., 2011. Composting as A Sustainable Waste Management Technique in Developing Countries.*Journal of Environmental Science and Technology* 4,2 : 93-102.

WELMAN, C., KRUGER,F., MITCHELL, B.,2005.*Research Methodology.* Southern Africa: Oxford University Press.

Appendices

3.11 Appendix A. The Research Questionnaire

This interview is based on a series of questions compiled by the researcher to gain an understanding of the Waste Management Processes adopted at Dr Reddy's Laboratories.

The contents of your input are treated as confidential and are for academic research purposes only.

Question 1:

Why do you believe there is a need for a Waste Management Strategy for Dr. Reddy's?

Question 2:

What Waste Management Processes are currently being implemented at Dr. Reddy's?

Question 3:

Which specific Act in Indian Waste Legislation regulates pharmaceutical waste?

Question 4:

How does Dr. Reddy's ensure Waste Minimisation in its manufacturing processes?

Question 5:

What recycling and re-use measure are in place at Dr Reddy's manufacturing plants?

Please select only one option per question from below to indicate your recommendations:

UNDERSTANDING OF WASTE MANAGEMENT PRACTICES AMONGST DR REDDY'S EMPLOYEES

- There is limited awareness of Waste Management Practices
- There is limited understanding of Waste Management Practices
- Casual and ad hoc
- Regular, clear – training departmental awareness
- There is emerging awareness and adoption of Waste Management Practices.

WHICH OF THE FOLLOWING IN YOUR OPINION NEED TO BE IMPROVED

- Waste Minimization
- Waste recycling
- Waste re-use
- Waste Disposal
- None of the above, Dr Reddy's is on par with other pharmaceutical companies in India.

PLEASE SELECT THE TOP TWO IDEAS YOU BELIEVE WOULD IMPROVE THE LEVELS OF THE ADOPTION OF WASTE MANAGEMENT PRACTICES BY STAFF AT DR. REDDY'S

- Annual Employee Satisfaction Survey
- Departmental Committees to oversee Waste Management projects, processes and operational issues.
- Ongoing staff training on Waste Management processes
- None of the above.

THANK YOU FOR YOUR VALUED PARTICIPATION!!!

3.12 Appendix B. DR. REDDY'S SOP FOR HANDLING OF HAZARDOUS WASTE.

Formulations
Unit II

DR.REDDY'S

STANDARD OPERATING PROCEDURE

Title: Handling, Storage and Disposal of Hazardous Waste				
SOP NO:	FT2SA009-00	Department:	Safety, Health & Environment	STAMP HERE
Effective Date:		Page No.:	1 of 5	

1.0 OBJECTIVE

To lay down the procedure for Handling, Storage and Disposal of Hazardous Waste generated

2.0 SCOPE

This procedure is applicable to Formulations Unit II for Handling, Storage and Disposal of Hazardous Waste generated within the factory and waste received from C&F Agents of Dr. Reddy's Laboratories Limited.

3.0 RESPONSIBILITY

3.1 SHE Incharge for coordinating & controlling procedure.
3.2 SHE Incharge for Handling & Safe Disposal of Hazardous Waste
3.3 HOD–SHE for compliance of the procedure

4.0 DEFINITION

Not applicable

5.0 PROCEDURE

5.1 GENERAL PRECAUTIONS DURING HAZARDOUS WASTE HANDLING

5.1.1 All the operators shall wear safety shoes, hand gloves & appropriate dust mask during hazardous waste handling.
5.1.2 While handling rejected & waste solvents earthing of container shall be ensured for static charge dissipation & operators shall wear solvent absorbing half face masks.
5.1.3 Any kind of spillages shall be avoided during handling of hazardous waste.
5.1.4 Hazardous waste handling shall be carried out by authorized persons only.
5.1.5 Hazardous waste handling area shall have lock & key provision & shall be opened only by authorized person
5.1.6 Different waste categories shall not be mixed together.

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User Department	Head of the Department	Quality Assurance
Sign:	Sign:	Sign:
Date:	Date:	Date:

FTCQA001/F01-00

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5.2 RECIEPT, TREATMENT & STORAGE OF HAZARDOUS WASTE DATE EXPIRED, DISCARDED, OFF SPECIFICATION DRUGS & MEDICINES (HW CATEGORY – 28.3, 28.4)

5.2.1 This category includes rejects received from manufacturing (In process rejected / waste tablets, capsules, blends, pellets, Solid raw material, Exciepients, Startup rejects, etc), rejected raw material from RM Warehouse & rejected finished goods from FG warehouse, Date expired medicines and drugs from Material Receiving Godown.

5.2.2 Collect Rejects / waste from manufacturing and Date expired drugs and medicines from MRG after Reciept, Segregation and Defacing as per SOP FT2SA004 along with duly filled disposal request as per FTCSA020/A01

5.2.3 All the rejects received from manufacturing shall be de labeled & stored in designated place

5.2.4 The waste received from RM warehouse shall be repacked in poly bags & containers and shall be sent for de labeling & detoxification.

5.2.5 The material received from FG warehouse shall be defoiled manually to segregate tablet, capsules & empty blisters, bottles, papers and shall be hand over to scrap yard for disposal.

5.2.6 The Tablets & capsules shall be crushed in crushing machine and send to Hazardous waste storage area along with duly filled disposal request as per FTCSA020/A01

5.2.7 The blends, pellets, powders along with Crushed / powdered material shall be packed into double poly bags.

5.2.8 All Bags shall be stored in designated place at Hazardous Waste storage area for disposal and ensure no spillage of powder/liquid on floor.

5.3 RESIDUES & WASTE (HW CATEGORY – 28.1)

5.3.1 This category includes waste generated / rejected coating solution from production, boiler soot from utility, water treatment resins from water systems, dust & powder from HVAC filters, dry dust scrubbers from mechanical department.

5.3.2 Collect the waste from generator along with duly filled disposal request as per the FTCSA020/A01

5.3.3 The reject coating solution shall be stored in poly bags OR refilled in 200 ltrs capacity HDPE drums.

5.3.4 Coating solution handling shall be executed in designated area. As these may contain solvent, proper safety precautions shall be taken.

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5.3.5 Boiler soot shall be repacked in poly bags & stored in designated area for disposal
5.3.6 Water treatment resins shall be stored in drums in designated area for disposal.
5.3.7 All the containers shall be labeled with appropriate Hazardous waste sticker on it

5.4 SPENT ORGANIC SOLVENTS (HW CATEGORY – 28.5)

5.4.1 This category includes waste organic solvents from Production, Pilot Plants & Quality Control Labs.
5.4.2 Receive the waste along with disposal request as per FTCSA020/A01.
5.4.3 All the waste shall be refilled in 200 ltrs capacity HDPE drums along with 28.1 category waste in designated area
5.4.4 All the containers shall be labeled with appropriate Hazardous waste sticker on it.

5.5 HDPE CHEMICAL CONTAINERS & LINERS (HW CATEGORY – 33.3)

5.5.1 This category includes empty solvent drums, raw material storage containers & liners.
5.5.2 Detoxification and Storage should be done as per SOP: FT2SA007

5.6 ETP SLUDGE (HW CATEGORY – 34.3)

5.6.1 This category includes sludge generated from ETP through drying beds.
5.6.2 Sludge collected from drying beds then packed in polythene covers
5.6.3 All polythene bags stored in designated place at Hazardous waste storage area for disposal

5.7 WASTE / USED OIL (HW CATEGORY – 5.1)

5.7.1 This category includes waste / used oil from oil fired boilers & air compressors in utility, waste diesels from generators, machine oils & grease wastes from concerned area.
5.7.2 Waste oils shall be collected from concerned area with disposal request & refilled in designated HDPE drums stored in designated place for disposal with safety precautions.

5.8 OTHER HAZARDOUS WASTE

5.8.1 This includes Used/ waste batteries, thermacoal, etc
5.8.2 Thermacol shall be received & stored in designated place for disposal.
5.8.3 Used/Lead acid batteries shall be stored in designated places for disposal

5.9 BIO-MEDICAL WASTE

5.9.1 This includes biomedical waste from Microbiology laboratory & Occupational Health Center
5.9.2 It shall be Segregated, Stored and Disposed as per SOP: FT2SA008

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5.10 DISPOSAL OF HAZARDOUS WASTE

5.10.1 All the wastes from HW category No. 28.1, 28.3, 28.4, 28.5, 34.3 shall be disposed periodically to Hazardous Waste Management Project (Ramky), Dundigal OR Cement Industry through an agreement as per CFO conditions by Andhra Pradesh Pollution Control Board.

5.10.2 The waste consignments shall be accompanied by TREM card & FORM 13 (6 copy manifest) as per requirement of Hazardous waste management rules, 2008 of Government of India.

5.10.3 Detoxified drums & liners shall be handover to scrap yard for disposal.

5.10.4 Waste/ Used Oil shall be disposed to authorized recyclers through an agreement along with TREM card & FORM 13 (6 copy manifest).

5.10.5 Waste/ Used batteries shall be handed over to manufacturer / dealer on buy back policy or disposed to CPCB (Central Pollution Control Board) approved recyclers wide an agreement as per The batteries Management & Handling rules, 2001 of Government of India.

5.10.6 Bio-Medical Waste shall be disposed periodically to APPCB approved facility as per Biomedical waste management & handling rules, 1998 of Government of India along with manifest copy through an agreement

6.0 REFERENCE(s)

SOP no. (Current Version)	Title
FTCSA020	Procedure for receipt treatment and disposal of solid/liquid wastes
FT2SA004	Receipt, Segregation, Defacing and Disposal of Expired, Discarded and Off-specification Drugs/Medicines
FT2SA007	Procedure for Detoxification of Empty Containers and Liners
FT2SA008	Receipt, Segregation and Disposal of Bio Medical Waste

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7.0 ABBREVIATION(s)

Abbreviation	Full Description
SOP	Standard Operating Procedure
No.	Number
ETP	Effluent Treatment Plant
LR	Lorry Receipt
DC	Delivery Challan
SCM	Supply Chain Management
TSDF	Transport Storage and Disposal Facility
SS	Stainless Steel
MRG	Material Receiving Godown
HW	Hazardous Waste
CFO	Consent For Operation
TREM Card	Transport Emergency Card
APPCB	Andhra Pradesh Pollution Control Board
C&F Agent	Clearing & Forwarding Agent

8.0 FLOWCHART(s)
Not Applicable.

9.0 ANNEXURE(s)
Not Applicable.

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