PERCEPTIONS AND EXPERIENCES OF REPORTING OF ADVERSE DRUG REACTIONS BY PUBLIC SECTOR PHARMACISTS IN A RURAL DISTRICT IN THE WESTERN CAPE

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A mini-thesis submitted in partial fulfilment of the requirements for the degree of Master of Public Health at the School of Public Health, University of the Western Cape.

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KEYWORDS

Adverse Drug Reactions
Pharmacovigilance
Spontaneous Reporting System
Pharmacists
In-depth Interviews
Purposive Sampling
Public Sector
Rural District
South Africa
Developing Country
ABSTRACT

Background
Adverse Drug Reactions (ADRs) contribute to potentially expensive hospital admissions and are regarded as a major public health priority. ADRs in South Africa are mainly detected by a spontaneous reporting system but it is plagued by under-reporting. Previous records indicated under-reporting of ADRs in the Cape Winelands District amongst healthcare workers. Pharmacists, in particular, did not report ADRs compared to other healthcare cadres whilst they are generally considered to be the custodians of medicines.

Study Aim
This study aimed to explore and describe the perceptions and experiences of rural public sector pharmacists’ reporting of ADRs and to understand why pharmacists in this rural health district under-reported ADRs.

Study Design
A qualitative study design was appropriate for this research question as the researcher wanted to gain an in-depth understanding of human behavior related to the phenomena of under-reporting.

Study Population and Sampling
The primary study population consisted of 24 public sector pharmacists in the Cape Winelands District. A purposive sampling strategy enabled the selection of 16 pharmacists ranging in gender, age, experience and rank. Eight pharmacists were supervisor pharmacists while the rest were production pharmacists, including a community service pharmacist and an intern pharmacist. Supervisor pharmacists are more involved with managerial tasks and the attendance of meetings compared to production pharmacists that focus on patient care and dispensing of medication. Two key informants involved in the Western Cape Pharmacovigilance System were included in the study.

One key stakeholder was a policy specialist pharmacist working at Directorate: Pharmacy Services and primarily involved with the Provincial Pharmacy and Therapeutics Committee. The other key policy stakeholder, at the time of the study, was the manager of the Medicines
Information Centre which forms part of the University of Cape Town’s (UCT) Pharmacology Division. Both were highly experienced pharmacists familiar with the pharmacovigilance system.

**Data Collection**

In-depth interviews were conducted using a semi-structured interview guide consisting of open-ended questions. The semi-structured interview guide was tested on a participant outside the primary study population. Interviews were conducted in English and Afrikaans. Interviews were tape-recorded and the interviewers made field notes to supplement the data recorded. Two researchers with experience in qualitative data collection, briefed by the investigator, interviewed the pharmacists who worked in the district and the investigator interviewed the two key stakeholders.

**Data Analysis**

The tape recordings were translated, where applicable, and all were transcribed verbatim by the investigator. The transcribed recordings were analyzed by the investigator by assigning codes to material on an Excel spreadsheet. This approach enabled the identification of themes which aided the understanding of the research phenomena.

**Ethics**

Ethical approval was obtained from the University of the Western Cape Senate Research Committee and permission from the Western Cape Department of Health Research Committee. Written informed consent (See Appendix 1, page 73) was obtained from each participant prior to conducting the interviews and interviewees were assured of confidentiality throughout the research.

**Key Results and Discussion**

Pharmacists in the study strongly acknowledged the importance of ADR reporting which is linked with pharmacists seeing themselves as the custodians of medication. Pharmacists in the study associated the reporting of ADRs with medication safety and felt responsible for ensuring it. In spite of this acknowledgement of the importance of ADR reporting, pharmacists rarely reported an ADR themselves. This finding was in line with previous research conducted and linked with barriers pharmacists faced in practice.
The study revealed that pharmacists identified ADR reporting opportunities during their normal clinical work and enabled other health care professionals (HCPs) to confirm the occurrence of an ADR and report it. Pharmacists primarily identified ADRs when they scanned patient folders for clues that could indicate that an ADR had occurred. Other research conducted confirmed that the use of patient records could be used in the identification of ADRs. This finding was important to inform future training workshops to promote reporting of ADRs.

Some pharmacists in the study associated an ADR with a therapeutic or clinical intervention. In general, therapeutic interventions usually involved a clinical action more closely associated with medical officers and were viewed by pharmacists in the study as being outside their legal and clinical scope of practice. A clinical intervention could include a change of medication, change of dose, and other prescription changes or might involve the medical officer referring the patient to a higher level of care depending on the severity of the suspected ADR experienced. A clinical intervention could include performing complex diagnostic tests, observations and laboratory investigations. Pharmacists’ association of an ADR experience with a clinical intervention was an important factor limiting their reporting of ADRs. The implication of this belief is that patients were referred from the pharmacy back to medical officers for the clinical intervention. In this way, although pharmacists do not directly report an ADR, their referral to medical officers would help improve reporting of ADRs.

An unexpected and contrasting finding compared to previous research was the strong belief of some pharmacists in this study that common ADRs should be reported. Pharmacists believed that by reporting common ADRs en masse, authorities might decide to remove the problematic medication from the approved public sector formulary. This was in contrast to previous research where pharmacists either acknowledged that authorities only want novel or serious ADRs from newly marketed medication or believed that reporting well-known ADRs was a waste of time.

Pharmacists reported that they faced several barriers in reporting ADRs. The main barriers that were mentioned were a lack of adequate feedback, heavy workload and time constraints, uncertainty in identifying the cause of an ADR and issues pharmacists had with the reporting
process. These barriers were consistent with previous research conducted.

Finally, pharmacists suggested various means of facilitating ADR reporting including use of electronic reporting aids, creating increased awareness amongst healthcare professionals, conducting continuous training and making amendments to the reporting form, some of which were in line with previous research conducted.

**Conclusion**
Exploring the perceptions and experiences of pharmacists with respect to the under-reporting of ADRs revealed key knowledge about the spontaneous reporting system that could be applied to strengthen the current reporting system and enable more reporting. Whilst it was clear that pharmacists play an important role as the gatekeepers and drivers of the reporting process enabling other HCPs to report ADRs, more should be done to empower pharmacists in managing ADR reporting opportunities. This could benefit the healthcare system in ensuring that more ADRs are reported, as well as decrease the waiting time of patients and the workload of medical officers. In addition, engaging with pharmacists and HCPs to overcome barriers to reporting would facilitate increased ADR reporting.

**Recommendations**
Several recommendations emerged from the study. Future circulars, training workshops and awareness posters about the ADR reporting process should inform all HCPs to report any medication suspected of being the cause of an ADR and not waste time in trying to identify the medication that caused it. A training workshop should be conducted with pharmacists to improve their skills in terms of identifying ADRs, how and what to report and of the appropriate referral of patients to the medical officers. An annual assessment on the availability of reporting forms in all health facilities should be conducted. In addition, the MIC should conduct a survey on the user-friendliness of the reporting form and enable HCPs to provide recommendations to help improve the reporting form template. Pharmacovigilance should be a standing item on the agendas of sub-district PTC meetings at which supervisor pharmacists should give quarterly updates to sub-district management on ADRs reported. As this study focused primarily on the experiences and perceptions of pharmacists in a rural health district, a follow-up study should explore perceptions and knowledge of medical officers and nurses of ADR reporting, specifically
on the availability and complexity of the reporting form. Finally, the MIC should explore the
development of a basic ADR causality assessment tool that could assist pharmacists and other
HCPs in identifying a possible ADR and improve confidence amongst pharmacists and HCPs in
reporting ADRs.
DECLARATION

I hereby declare that this study “PERCEPTIONS AND EXPERIENCES OF REPORTING OF ADVERSE DRUG REACTIONS BY PUBLIC SECTOR PHARMACISTS IN A RURAL DISTRICT IN THE WESTERN CAPE” is my own work and it has not been submitted for any degree or examination to any other university, and that all sources I have used or quoted have been indicated and acknowledged by referencing.

Full Name: Charles Jonathan Williams

Signature: [Signature]

Date: 26 November 2015
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<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>ART</td>
<td>Antiretroviral Therapy</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<td>CDC</td>
<td>Community Day Centre</td>
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<td>CNP</td>
<td>Clinical Nurse Practitioner</td>
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<td>CWD</td>
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<td>HAST</td>
<td>HIV, AIDS, STI, TB</td>
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<td>HIV</td>
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<td>K</td>
<td>Key Stakeholder</td>
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<td>M&amp;M</td>
<td>Mortality and Morbidity</td>
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<td>MIC</td>
<td>Medicines Information Centre</td>
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<td>MCC</td>
<td>Medicines Control Council</td>
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<td>NADEMC</td>
<td>National Adverse Drug Event Monitoring Centre</td>
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<td>NGO</td>
<td>Non-Governmental Organization</td>
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<td>NHP</td>
<td>Natural Health Product</td>
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<td>NPC</td>
<td>National Pharmacovigilance Centre</td>
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<td>PBPA</td>
<td>Post Basic Pharmacist Assistant</td>
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<td>PP</td>
<td>Production Pharmacist</td>
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<td>PPB</td>
<td>Pharmacy and Poisons Board</td>
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<td>PV</td>
<td>Pharmacovigilance</td>
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<td>SAAHIP</td>
<td>South African Association of Hospital and Institutional Pharmacists</td>
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<td>SAMF</td>
<td>South African Medicines Formulary</td>
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<td>Acronym</td>
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<td>SAPC</td>
<td>South African Pharmacy Council</td>
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<td>SP</td>
<td>Supervisor Pharmacist</td>
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<td>SRS</td>
<td>Spontaneous Reporting System</td>
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<td>TB</td>
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<td>UCT</td>
<td>University of Cape Town</td>
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<td>UMC</td>
<td>Uppsala Monitoring Centre</td>
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<td>UWC</td>
<td>University of the Western Cape</td>
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<td>World Health Organization</td>
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DEFINITIONS OF KEY TERMS

Community Day Centre- a healthcare facility where healthcare services are provided by clinical nurse practitioners (CNPs), with the support of full-time medical officers and pharmacists and where patients have access to X-ray services. A CDC normally provides a service between 08h00 and 16h00.

Community service pharmacist- pharmacist restricted to work only in the public sector at designated sites, after successful completion of an internship.

Intern- pharmacist category post university qualification with a limited scope of practice, supervised by another designated, registered pharmacist called a tutor.

Pharmacovigilance - Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. (WHO, 2008)

Poly-pharmacy- the practice of prescribing multiple medications to patients suffering from more than one illness, at the same time.

Production pharmacist – a person who is professionally qualified to prepare and dispense medicinal drugs with a scope of practice prescribed in terms of Section 35A of the Pharmacy Act 53 of 1974.

Responsible pharmacist- is a pharmacist who is responsible to the South African Pharmacy Council for complying with all the provisions of the Pharmacy Act and other legislation applicable to services that specially pertain to the scope of practice of a pharmacist and legislation applicable to the pharmacy that is under his or her personal supervision.

Spontaneous Reporting- a reporting system based on voluntary reporting as opposed to forced reporting, where healthcare workers are forced to report ADRs.

Supervisor pharmacist- a category of pharmacist in the public sector managing other pharmaceutical staff and registered as the responsible pharmacist with the South African Pharmacy Council.
CHAPTER 1: INTRODUCTION

1.1. Introduction

According to the World Health Organization (WHO) definition, an Adverse Drug Reaction (ADR) is any noxious, unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy (Abdel-Latif & Abdel-Wahab, 2015; WHO, 2008). ADRs contribute to potentially expensive hospital admissions of affected patients (Zolezzi & Parsotam, 2005; Abdel-Latif & Abdel-Wahab, 2015). ADRs have been reported to be associated with a prolonged length of hospital stay, which leads to higher healthcare costs (Abdel-Latif & Abdel-Wahab, 2015; Doherty, 2009; Zolezzi & Parsotam, 2005). Furthermore, ADRs have a detrimental effect on a country’s economy due to loss of the working population’s income and loss of production days (Zolezzi & Parsotam, 2005). As most ADRs can be considered as preventable, it is thus essential that any healthcare system needs to incorporate an effective and adequate pharmacovigilance management programme (Jose et al., 2014).

Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding and prevention of Adverse Drug Reactions (ADRs) and drug-related problems (Abdel-Latif & Abdel-Wahab, 2015; WHO, 2008).

Pharmaceutical companies are required by law in all countries to test their medications on healthy and patient volunteers before making them available to the general public (WHO, 2008). All registered medicines first have to undergo pre-clinical studies and pre-marketing clinical trials to ensure that they comply with international safety standards (Suleman, 2010). A clinical trial is any research study that prospectively assigns human participants or groups of humans to any health-related interventions to evaluate the effects on certain health outcomes (WHO, 2012). Clinical trials that are conducted under controlled conditions cannot test for all possible ADRs under real-world conditions as experienced by the diverse, greater population (Sarker et al., 2015; Suleman, 2010). Pregnant women, children and patients affected by co-morbid conditions, patients on multiple drug therapy and patients with decreased renal and hepatic function are often
After the medication has been registered and is commercially available, the exclusion criteria applied during clinical trials no longer exist to prevent potentially at-risk patients from being exposed to it during extended therapy (Zolezzi & Parsotam, 2005). This increases the possibility of previously undetected ADRs to surface and create detrimental effects on quality of life (Zolezzi & Parsotam, 2005). ADRs may also occur at a very low frequency, which will make it difficult to detect them in clinical trials due to the relatively small numbers of patients included in them (Zolezzi & Parsotam, 2005).

WHO initiated an international programme for monitoring the safety of medicines in 1968 (Oreagba et al., 2010). The programme is coordinated by the Uppsala Monitoring Centre located in Sweden (Oreagba et al., 2010). The Uppsala Monitoring Centre regularly publishes an overview of how the various national reporting systems are functioning (Van Grootheest et al, 2004). Most pharmacovigilance programmes around the world rely on spontaneous reporting of ADRs from healthcare professionals (Pal et al., 2013; Green et al., 2001). Only a small number of African countries, including South Africa, have formal pharmacovigilance systems in place (Severe et al, 2008). These spontaneous reporting systems (SRS) play an important role in identifying ADRs efficiently and effectively (John et al., 2012; Palaian et al., 2011; Green et al., 2001). Spontaneous reporting systems have been associated with the phenomenon of under-reporting of ADRs (Molokhia, 2009; Zolezzi & Parsotam, 2005).

The Medicines Control Council (MCC), the drug regulatory authority in South Africa, oversees and governs pharmacovigilance in accordance with the Medicines and Related Substances Control Act, Act 101 of 1965 (Act 90) as amended (Maigetter et al., 2015). The MCC has the responsibility to ensure the safety, efficacy and quality of all medicines in South Africa (Mehta, 2011). The pharmacovigilance programme of the MCC is coordinated by the National Pharmacovigilance Centre (NPC), which is based in Pretoria (Mehta, 2011). The NPC oversees the National Adverse Drug Monitoring Centre (NADMC), which is based at the University of Cape Town (Maigetter et al., 2015; Mehta, 2011). The NADMC is responsible for the collation of ADR information, the management of the national ADR database and the assessment of ADR related risks and causality trends (Maigetter et al., 2015; Mehta, 2011). The Medicines Information Centre (MIC), which is also based at the University of Cape Town, collects only
spontaneous ADRs from anti-retroviral medication, which are also forwarded to the NADMC (Maigetter et al., 2015).

The NADMC is required to report ADR information to the MCC and the Uppsala Monitoring Centre (UMC) (Maigetter et al., 2015). Information from the national ADR database is routinely forwarded to the international ADR database maintained by the UMC (Mehta, 2011). The MCC’s pharmacovigilance committee, which consists of a pharmacist and six external pharmacovigilance experts, advises the MCC on the prevention and minimizing of ADR risks (Maigetter et al., 2015; Mehta, 2011). In certain cases, spontaneous ADR reporting can lead to action being taken in the form of withdrawing the potentially unsafe medication from the market (Maigetter et al., 2015; Mehta, 2011).

The success of any pharmacovigilance system requires a coordinated multidisciplinary team approach where various healthcare practitioners, including pharmacists, play a significant role (Jose et al., 2014). Pharmacists have a key role in the prevention of ADRs and improving the reporting of ADRs due to their easy access to patient medical records and their inherent pharmacological knowledge (Rajiah et al., 2015; Jose et al., 2014; Elkalmi et al., 2011). Pharmacists’ actual role in pharmacovigilance activities, their knowledge about the pharmacovigilance system and the factors that influence their contribution to ADR reporting may be different among countries (Jose et al., 2014). Suleman (2010) reported on the role of the pharmacist as a reporter of ADRs in the international context. Whereas pharmacists were traditionally associated with the dispensing of medicines and ensuring that standards are adhered to, this role has moved to include being a consultant on pharmacotherapy for both patients and other healthcare practitioners (Suleman, 2010). As pharmacists are internationally recognized as being the experts on medicines the question is asked what role pharmacists could or should play in ensuring the safe use of medicines and specifically, in the direct reporting of ADRs (Suleman, 2010).

According to Van Grootheest et al. (2004) and Zolezzi & Parsotam (2005) pharmacists should play a central and coordinating role in drug safety by contributing to the prevention, identification, documentation and reporting of ADRs. Internationally, there are various degrees
of reporting of ADRs by pharmacists (Suleman, 2010). In some countries, pharmacists contribute substantially to ADR reporting. Examples are the United States, Canada and the United Kingdom, where hospital pharmacists are primarily responsible for reporting of ADRs (Suleman, 2010). Community pharmacists in the Netherlands, Japan and Portugal also play a large role in the reporting of especially ADRs related to over the counter medication (Suleman, 2010). However, not much has been published about the reporting of ADRs by pharmacists in South Africa (Suleman, 2010). In the World Health Organization’s Drug Monitoring Programme study of 2002, South Africa ranked 29th out of a total of 39 countries in terms of pharmacists involvement in the reporting of ADRs (Suleman, 2010). As South Africa is lagging behind other upper middle-income countries concerning ADR reporting rates, the pharmacist as part of a multidisciplinary team could play a significant role in improving ADR reporting leading to increased medication safety (Aagaard et al., 2012).

Antiretroviral therapy (ART) was rolled-out on a large scale in the public sector in the Western Cape Province in April 2004 (Venter, 2014; Mehta et al., 2008). A convergence of the HIV/AIDS and TB epidemics in South Africa has also been seen recently further complicating the management of pharmacovigilance (Mehta et al., 2008). Although developed countries have gained some experience with the use of ARTs, little is known about the safety of ART in developing countries (Ruud et al., 2010). The frequency, nature and population at risk of drug-related harm could thus be very different compared to developed countries, where the burden of the two epidemics are very low (Mehta et al., 2008). Furthermore, a high number of patients on ART have been shown to experience at least one ADR (Tadesse et al., 2014). The management of ADRs in patients on ART is especially important to ensure patients’ continuation and motivation to stay on therapy (Ruud et al., 2012). It is essential that a well-functioning pharmacovigilance system should be in place to monitor HIV/AIDS treatment programmes (Dheda et al, 2013). The HIV/AIDS and TB epidemics have a major impact on the epidemiology of ADRs and contribute significantly to patient morbidity and hospitalization in South Africa (Mehta et al., 2008). Medication used in the treatment of multidrug resistant TB is often associated with commonly occurring ADRs that have an impact on the adherence of patients (Tag El Din et al, 2015). ARV drugs and medication used to treat opportunistic infections commonly associated with HIV-infected individuals showed a greater tendency to
produce ADRs compared with drugs usually associated with producing ADRs in developed countries (Mehta, 2011; Ruud et al, 2010; Mehta et al., 2008). The high incidence of ADRs produced by medication associated with HIV/AIDS and TB epidemics coupled with the fact that most ADRs are preventable suggest greater involvement of pharmacists to report ADRs in South Africa (Mehta, 2011). Ruud et al. (2010) showed that the occurrence of ADRs and a lack of knowledge of patients concerning ADR information had a direct impact on treatment success and adherence to treatment. By promoting adherence to pharmacotherapy and improved prescribing and monitoring of patients’ medication, pharmacists can play a substantial role in improving patients’ treatment outcomes (Mehta, 2011).

Resource constraints and treatment programmes focussing on HIV/AIDS, malaria and tuberculosis impacted on the development of pharmacovigilance systems in developing countries (WHO, 2011). Most countries in the developed and developing world have spontaneous reporting systems in place which is cost effective and relative easier to set-up compared to other systems (WHO, 2011). Pharmacovigilance systems in lower income countries have however focussed more on medication used in public health programmes such as HIV/AIDS and malaria (WHO, 2011).

Furthermore, due to the widespread use of herbal medicines, some African countries such as South Africa, Nigeria and Cameroon incorporated a focus on herbal and traditional medicines as part of their pharmacovigilance systems as recommended by guidelines published by the WHO (Kamsu-Foguem & Foguem, 2014; Shaw et al., 2012). Pharmacovigilance systems in sub-Saharan Africa still need to see major improvement to ensure medication safety (Appiah, 2012.) Appiah (2012) reported on an evaluation that was done on 46 sub-Saharan countries’ readiness to ensure adequate medication safety. The results were not promising with most of the countries assessed found to have an inadequate pharmacovigilance system in place. Only four countries were deemed to have the ability to ensure proper pharmacovigilance safety measures (Appiah, 2012).

1.2. Study setting

The study was conducted in the Cape Winelands District, Western Cape Province focusing on
the Department of Health’s clinic and hospital pharmacists. The Cape Winelands District is one of four rural health Districts located in the Western Cape Province. The district has a population of 845,237 according to the latest census (See Appendix 2, page 75). It consists of five subdistricts namely the Breede Valley, Langeberg, Witzenberg, Drakenstein and Stellenbosch subdistricts. The Cape Winelands District has four district hospitals, one specialized tuberculosis hospital, four community day centres (CDC), 45 fixed clinics, five satellite clinics and 26 mobile services. The Cape Winelands District employs 24 pharmacists with various degrees of experience, of which eight are supervisor pharmacists, supported by 54 post-basic pharmacist assistants.

Until recently two different ADR reporting systems existed in the Western Cape Province’s Department of Health, one each for ART-related medication and the other for non ARV-related medication. (See Appendix 3, page 76 and Appendix 4, page 78). The different reporting systems had different reporting forms which made it more complicated to report adequately. (See Appendix 3, page 76 and Appendix 4, page 78). There is a new initiative in the Western Cape’s Department of Health to merge the two reporting systems into one system to make the reporting process less complicated. The current Western Cape Department of Health pharmacovigilance circular was issued in 2013 just after this study’s data collection was completed. (See Appendix 5, page 86). It is envisaged that pharmacists will play a more prominent and central role in the proposed reporting system.

1.3. Problem Statement

A Spontaneous Reporting System (SRS) of ADRs forms the backbone of South Africa’s drug safety programme (Maigetter et al., 2015). It is well known that SRSs of ADRs are plagued by the phenomenon of under-reporting (Ahmad et al., 2013; WHO, 2011; Zolezzi & Parsotam, 2005). Under-reporting delayed early detection of an ADR and led to an underestimation of the size of the problem in New Zealand (Zolezzi & Parsotam, 2005). Whilst in some countries pharmacists do report extensively (United States, Canada and United Kingdom), the reporting of ADRs in South Africa can be described as poor (Maigetter et al., 2015; Aagaard et al, 2012; Suleman, 2010). Furthermore the HIV/AIDS and TB epidemics add substantially to South
Africa’s burden of disease, as seen in the Eastern Cape Province, with ADRs amongst HIV–
positive patients on ART being an important cause of hospitalizations (Ruud et al., 2010). It has
also been shown that lack of information on ADRs amongst patients has a direct impact on these
patients’ adherence on ART, which is problematic (Ruud et al., 2010). Pharmacists in the Cape
Winelands District could potentially play a major role in reporting ADRs, assisting other
healthcare workers in reporting suspected ADRs and, in particular, strengthening the ART
programme.

Previous research conducted has highlighted several barriers that HCPs, including pharmacists,
face that contribute to the under reporting of ADRs (Elkalmi et al., 2011; Walji et al., 2011;
Green et al., 2001). Putting measures in place to reduce the impact of under-reporting of ADRs is
not a straightforward process as its extent and possible local variables that impact on it are
usually not known (Zolezzi & Parsotam, 2005). Having a better understanding of potential
variables that could impact on under-reporting could assist healthcare managers to improve the
pharmacovigilance system as reported conducted in a study in a New Zealand setting 10 years
ago (Zolezzi & Parsotam, 2005). The primary motivation for this particular study is to explore
the perceptions and experiences of pharmacists in reporting ADRs, to gain an understanding of
the role that pharmacists play and their knowledge of the pharmacovigilance reporting system,
and to better understand the barriers pharmacists might face that prevent them from participating
in the reporting of ADRs. As it is expected that Western Cape public sector employed
pharmacists will play a more prominent and central role in the reporting and coordinating of
ADRs in the future, it is hoped that this study will provide recommendations to strengthen Cape
Winelands District’s pharmacovigilance programme.
CHAPTER 2: LITERATURE REVIEW

2.1. Introduction

Previous research has reported extensively on various aspects of pharmacovigilance including the role various HCPs play, their knowledge and perceptions, including pharmacists, the reasons for under-reporting, the barriers HCPs face in practice and facilitators that could improve ADR reporting. These aspects vary between different settings and are influenced by a host of factors. This literature review focuses on factors influencing under-reporting of ADRs under three main themes: issues relating to the pharmacovigilance system, barriers in reporting, and facilitators to ADR reporting.

2.2. Issues relating to the pharmacovigilance system

2.2.1. Familiarity with the ADR reporting system

Whilst there are differences between countries in how their pharmacovigilance systems are organized and run and how they expect their HCPs to report ADRs, it is essential for HCPs to fully understand how a country’s pharmacovigilance functions for them to report ADRs adequately (Van Grootheest et al, 2004). It has been found that when HCPs do not know that such a system exists and how the reporting system is organized, it has a detrimental effect on the number of ADRs that will be reported (John et al., 2012; Fadare et al, 2001; Palaian et al., 2011). Elkalmi et al. (2011) found that most respondents in their study were not aware of a pharmacovigilance system and showed a lack of awareness of the previously issued reporting guidelines (Elkalmi et al, 2001). HCPs need to be familiar with certain aspects of the pharmacovigilance system such as the ADR reporting form in order to report successfully (Elkalmi et al, 2011). They also found that most participants were not aware of ADR reporting forms while some had come across them by chance. This lack of knowledge and familiarity of how the reporting process worked had a detrimental impact on reporting (Elkalmi et al., 2011).
2.2.2. Gaps in the ADR reporting system

Gaps in the pharmacovigilance reporting system could include the unavailability of or no access to reporting forms, a lack of an address where to send the ADR reports and a lack of guidelines to ensure that continuous awareness is maintained (Elkalmi et al, 2011). Elkalmi et al. (2011) mentioned a lack of address to send the reports to and unavailability of the reporting forms as gaps in the reporting system in Malaysia. In resource-poor settings such as in Africa, where telecommunication infrastructure is often found wanting, a lack of resources might result in completed forms not reaching the central reporting centre and feedback might not reach the reporters (Sevene et al, 2008). Oreagba (2010) reported that 88% of pharmacist respondents in a study done in Nigeria claimed that they did not have access to ADR reporting forms and highlighted this as an important factor why they did not report.

2.2.3. Complexity of the ADR reporting system

Where healthcare workers, including pharmacists, perceive the reporting process or the reporting form as too complicated, results have shown that this negatively affects their willingness to report ADRs (Elkalmi et al., 2011; Ruud et al., 2010). A complex form may be perceived by pharmacists as requiring more time to complete, in an already challenging workplace environment where time is limited (Walji et al., 2011). Even if the reporting form is straightforward to complete, the reporting route might be perceived as being complicated by HCPs (Elkalmi et al., 2011).

2.2.4. Attitudes and behaviors towards ADR reporting

An international journal review found that under-reporting of ADRs is strongly associated with specific attitudes of HCPs to ADRs and the reporting system (Lopez-Gonzalez et al., 2009). For pharmacists to report ADRs on a continuous basis, it is essential that they view the reporting of ADRs as part of the pharmaceutical care provided by them. (Walji et al., 2011). Elkalmi’s et al. (2011) study in Malaysia highlighted the fact that a pharmacist’s perception of his or her professional role played the greatest part in determining whether ADRs for natural health products would be reported or not. Where pharmacists exhibited a broader view of their
professional role and responsibility, it was found that they were more likely to report ADRs and less likely to be influenced by workplace challenges that prevented others from reporting (Walji et al., 2011). Elkalmi et al. (2011) reported that most pharmacists saw the reporting of ADRs as part of their pharmaceutical care role and acknowledged the importance of ADR reporting.

Summers et al. (2013) reported on an interactive workshop on pharmacovigilance at the SAAHIP 2013 National Conference which allowed participants to decide for themselves whether pharmacovigilance is a vital tool for the pharmacist or a wasted effort (Summers et al, 2013). The survey found that few of the participants practise pharmacovigilance actively, despite the fact that the great majority (n = 90) rated pharmacovigilance as either important (39%) or very important (58%) in their everyday work (Summers et al, 2013).

Even though pharmacists agreed that it was part of their professional responsibility to report ADRs and acknowledged the importance of ADR reporting, reporting was found to have been an uncommon occurrence in their careers. (Suyagh et al., 2015; Jose et al., 2014; Elkalmi et al., 2011; Walji et al., 2011; Green et al., 2001)

Pharmacists acknowledge that the responsibility for reporting ADRs is shared with other healthcare providers such as doctors and nurses (Walji et al., 2011). This overlapping responsibility leads many pharmacists to refer a potential ADR to another healthcare provider or co-operate with them rather than reporting it themselves (Walji et al., 2011). On the other hand, an early study indicated that some pharmacists do not report ADRs because they assume another HCP will report the suspected ADR (Green et al., 2001). This could also have been due to some pharmacists feeling apprehensive about sending in ‘inappropriate’ reports (Green et al., 2001). Passing the responsibility to others might lead to a loss of follow-up on the ADR (Walji et al., 2011). Where pharmacists took a more involved role in reporting ADRs they were less likely to pass on the responsibility of reporting ADRs to other healthcare workers. (Walji et al., 2011). Although pharmacists might acknowledge the importance of reporting of ADRs, they do not necessarily regard it as a major priority compared to other more pressing matters such as stock control, paperwork, and human resource management matters (Walji et al., 2011).
Walji et al. (2011) reported on pharmacist interventions when confronted by patients reporting an NHP-related ADR. Pharmacists either recommended that patients discontinue using the suspected product, or advised the use of another product to lessen the effects of the reaction or replacing the product with a different one (Walji et al., 2011). Although pharmacists were concerned about the safety of the presenting patients, they nevertheless failed to see the importance of reporting the ADR to make a contribution to the safety of other patients (Walji et al., 2011).

### 2.3. Barriers to reporting ADRs

Several barriers have been identified which hinder pharmacists from reporting ADRs. These include a lack of knowledge and skills, a heavy workload or time constraints and a lack of feedback. Elkalmi et al. (2011) reported that previous studies identified a number of barriers that prevent pharmacists from reporting ADRs, including the unavailability of the reporting form, pharmacists not knowing what to report on, fear of legal liability, lack of time, pharmacists being unsure about the cause of the ADR and ADRs being too well known or simplistic to report on.

#### 2.3.1. Heavy workload and time constraints

A heavy workload and time pressures continually came up as a major barrier to reporting across various categories of healthcare providers in different countries (Walji et al., 2011). Respondents previously reported that they just did not have the time to report ADRs (Green et al, 2001). In a resource-constrained environment where pharmacies are under-staffed, other matters seem to have a higher priority, as reported earlier (Walji et al., 2011). In South Africa, work and time constraints as experienced by healthcare workers have been reported as a serious limiting factor in reporting ADRs (Suleman, 2010). This can be attributed to working in stress full environments, and managing increasing patient numbers and dealing with staff shortages. (Ruud et al., 2010). Elkalmi et al. (2011) reported that some pharmacists perceive medical officers as being very busy which impacts on the working relationship between the medical officers and pharmacists as medical officers might not respond to pharmacists’ queries. Most pharmacists complained of a heavy workload and the reporting of ADRs was seen as just additional paperwork added to the busy schedule of healthcare workers (Ruud et al., 2010).
2.3.2. Lack of knowledge and skills

A lack of clinical knowledge and a lack of understanding of what should be reported were found to have a major impact on ADR reporting amongst healthcare workers (Suleman, 2010; Green et al., 2001). Oreagba et al. (2010) reported that pharmacovigilance knowledge amongst community pharmacists in Nigeria was poor which partially explained the poor reporting of ADRs. Where knowledge is lacking, HCPs could fail to identify an ADR in the first place (Ruud et al., 2010). A lack of knowledge could be attributed to previous healthcare policy priorities (Ruud et al., 2010). With the roll-out of the ART programme in the Eastern Cape, initial emphasis was placed on more to the delivery of ARV’s without the necessary focus on pharmacovigilance practices (Ruud et al., 2010). Ruud et al. (2010) reported on nurses who generally prescribed pain medication for the relief of pain without considering that it could be as a result of an ADR (Ruud et al., 2010). A lack of knowledge could also lead to a lack of confidence to refer and report ADRs (Ruud et al., 2010). Ruud et al. (2010) found that although patients’ ADRs might have been identified, patients were referred for treatment purposes only, without formally reporting the ADR for pharmacovigilance purposes (Ruud et al., 2010).

Pharmacists did not always understand clearly what should be reported (Zolezzi & Parsotam, 2005; Green et al., 2001). In South Africa, most HCPs, including pharmacists, have indicated that they had a lack of understanding of what should be reported and that they lacked the knowledge and skills to identify ADRs (Suleman, 2010). Where ADRs are considered to be well-known and of little importance clinically, the chances that they will be reported could be reduced (Elkalmi et al., 2011). HCPs tended to be more likely to report an ADR if it is serious or rare (Walji et al., 2011). Furthermore, although a suspected ADR might be classified as serious or rare, this does not necessarily mean that it will be reported due to pharmacists wanting to be sure that the causality can be traced back to the drug in question (Walji et al., 2011). Green et al. (2001) reported that a higher proportion of pharmacists compared to hospital doctors report serious reactions and a lower proportion of reports involved reactions attributed to newly marketed drugs (Green et al, 2001).
Pharmacists were found to want to be sure about what could have potentially caused the suspected ADR before they reported the reaction to prevent them from looking incompetent (Green et al., 2001). Elkalmi et al. (2011) reported that most pharmacists only reported if they were sure about the cause of the ADR. A lack of knowledge of the legal liabilities concerning ADR reporting could also have a negative impact on reporting (Ahmad et al., 2013; Zolezzi & Parsotam, 2005). Where pharmacists were unsure of any potential comebacks when they reported ADRs, they might have been reluctant to report ADRs in the first place (Zolezzi & Parsotam, 2005). This can be overcome by establishing a reporting culture where HCPs feel confident to report ADRs without facing any penalties (Ashcroft, 2006).

### 2.3.3 Lack of feedback

An important barrier routinely mentioned in previous research is the lack of feedback provided to HCPs of ADRs (Ruud et al., 2010; Zolezzi & Parsotam, 2005; Green et al., 2001). No or minimal feedback to reporters, including confirmation of reports received, discourages the continuous reporting of ADRs (Elkalmi et al., 2011; Ruud et al., 2010; Suleman, 2010; Olsson et al., 2010). Individual feedback should be provided to pharmacists who submitted reports. General feedback in the form of guidelines based on trends were recommended as part of a pharmacovigilance plan (Elkalmi et al., 2011). Poor communication and feedback were found in a survey conducted at a national pharmacovigilance stakeholders workshop held in South Africa in 2012, to be one of the major weaknesses in current pharmacovigilance systems (Mehta et al., 2013).

### 2.4. Facilitators to reporting ADRs

Various facilitators or enablers have been reported to help improve the reporting of ADRs. These can be classified as ways that aim to strengthen the reporting system, educational interventions and incentives to improve reporting.

#### 2.4.1 Strengthening and facilitating the reporting system

Continuous awareness campaigns were needed to be implemented to raise the importance of ADR reporting amongst HCPs (Fadare et al., 2011). Healthcare workers should also have an adequate understanding of the reporting process and how it is organized (Elkalmi et al., 2011). It
was recommended that the reporting form should be as simple as possible to enable a more convenient reporting process (Elkalmi et al., 2011). It has been recommended that ADR reporting forms should be available and always accessible and that there should be no doubt as to where the reporting form needs to be sent (Elkalmi et al., 2011). One way of improving the accessibility of the reporting form was to provide reporters with the option of web-based reporting (Molokhia, 2009).

A focal person being tasked to facilitate and strengthen the reporting process should be especially considered in resource-constrained environments (Sevene et al, 2008). The pharmacist can play such a key role in various settings and help coordinate the reporting process and compensate for any inherent flaws and challenges in the system (Sevene et al, 2008). The presence of clinical pharmacists in the wards and their constant encouragement might help improve the rate of reporting amongst other HCPs while at the same time lead to a decrease in the avoidable Adverse Drug Events including ADRs. (Arulmani et al., 2008; Green et al., 2001).

2.4.2 Educational interventions

It has been shown that educational interventions considerably improve rates of reporting although this benefit decreases with time (Kabanywanyi et al., 2010; Molokhia, 2009). Continuous education is needed to increase the clinical knowledge of healthcare workers to enable them to identify ADRs and have the confidence to report them (Oreagba et al., 2010; Molokhia, 2009; Green et al, 2001). Training was in the form of regular workshops and seminars aimed at improving the pharmacist’s detection skills and updates related to the ADR reporting process were disseminated (Elkalmi et al, 2011). Sevene (2008) reported that an improvement was seen in the rate of reporting after a pharmacovigilance training session was conducted (Sevente et al., 2008). ADR reporting guidelines in the form of booklets and posters were recommended to be readily available and placed in easy to find locations in healthcare facilities (Fadare et al., 2011).

2.4.3 Providing incentives to report

Elkalmi et al. (2011) reported that the majority of the pharmacists interviewed did not prefer monetary incentives but rather expressed a need for incentives in the form of awards and journal subscriptions (Elkalmi et al., 2011). However, community pharmacists in a Nigerian study
believed that remuneration might well lead to an increase in the number of reports (Oreagba et al., 2010). Green et al. (2001) recommended that health care practitioners, including pharmacists, should be continuously motivated by management to report ADRs. In South Africa, it has been reported that HCPs are poorly motivated to produce quality data because most data collected are irrelevant to their own information needs (Suleman, 2010).

2.5. New initiatives and recent developments

Several recent innovations and developments have been reported on that have relevance for South Africa. These include the Kenyan electronic reporting system, recommendations for a new South African National Pharmacovigilance Plan and a decentralized pharmacovigilance reporting system piloted in Mpumalanga province, South Africa.

2.5.1 The Kenyan Electronic reporting system

The Kenyan Pharmacy and Poisons Board (PPB) began establishing a process of monitoring and reporting ADRs in 2004, and the Kenyan National Pharmacovigilance System was officially launched on June 9, 2009 (Otieno, 2013). Kenya became the first country in Africa, and in the world, to use a digital reporting tool for pharmacovigilance based on mobile technology (Otieno, 2013).

Like other countries, Kenya relied on manual reporting using printed forms in the past (Otieno, 2013). Two forms were historically used, a yellow form for reporting suspected ADRs and a pink form for reporting suspected poor-quality medicines (Otieno, 2013).

Managing a manual system is a cumbersome and tedious process compared to an electronic system, due to the fact that the authorities had to make sure that the forms were printed and transported to various health care facilities throughout the country. Furthermore, reports submitted to the National Pharmacovigilance Centre had to be entered manually into the WHO recommended database, which all added to costs and loss of time (Otieno, 2013). The new digital system, which was launched on April 23, 2013, is a paperless system and can be downloaded either on a computer or a smart phone, or the report can be made directly to the PPB on their website.
Significant improvements were immediately seen after the implementation of the electronic system such as an increase in the number of ADR and poor product quality reports submitted which resulted in the PPB quarantining, recalling, or withdrawing some medicines (Otieno, 2013). One specific action taken because of reports submitted via the new electronic system resulted in the closure of a pharmaceutical company that was not meeting legislative requirements.

2.5.2 Recommendations for a South African National Pharmacovigilance Plan

Mehta (2013) reported on the findings and recommendations of a South African national pharmacovigilance workshop that was held in 2012. The aim of the workshop was to obtain an overview of non-regulatory pharmacovigilance activities being conducted in the public sector in support of a national pharmacovigilance plan (Mehta et al., 2013). The workshop identified key strengths, challenges, and opportunities in improving the coordination of pharmacovigilance activities and operations (Mehta et al, 2013).

The workshop had the opinion that the national pharmacovigilance plan must encompass five key principles (Mehta et al, 2013). Firstly, all pharmacovigilance systems should be incorporated into a unified national system (Mehta et al., 2013). Furthermore, the data generated from the national pharmacovigilance system should contribute to treatment, policy decision-making and improved patient care especially at primary healthcare level (Mehta et al., 2013). The national pharmacovigilance system should incorporate both passive and active surveillance methods and should continue with systems that already exist and have shown success (Mehta et al., 2013). What is also needed is investment in capacity building and training in pharmacovigilance and pharmaco-epidemiology which will contribute to the success of the system (Mehta et al., 2013). Lastly, feedback and communication to all stakeholders and role-players must be prioritized to ensure the success of the new pharmacovigilance programme (Mehta et al., 2013).

One of the recommendations of the workshop was the creation of a national pharmacovigilance website that can enable the sharing of information sharing between role-players and stakeholders
(Mehta et al., 2013). This electronic data management system should be developed by the
Department of Health and make provision for routine analysis, reporting of data and feedback to
reporters and other relevant stakeholders (Mehta et al., 2013).

The National Department of Health has already started implementing some of the workshop’s
recommendations (Mehta et al., 2013). This included the appointment of a co-coordinator to
facilitate implementation and the creation of a national decentralized Targeted Spontaneous
Reporting system for HIV and TB in six provinces (Mehta et al., 2013). Spontaneous reports
generated by this decentralized reporting system are reviewed by a sub-district multidisciplinary
health team to identify trends, preventable factors and system errors (Mehta et al., 2013). In
addition to the above, the National Department of Health is also implementing a national
pregnancy exposure registry and birth defect surveillance programme at certain specified sites to
assess the safety of medicines used in pregnancy (Mehta et al., 2013).

2.5.3 Decentralized pharmacovigilance pilot programme in Mpumalanga province

Dheda (2013) reported on a pilot-project, which involved setting up a decentralized
pharmacovigilance reporting programme focusing on ART in Mpumalanga province in South
Africa. As part of the programme intervention, HCPs, which included pharmacists, were first
trained in pharmacovigilance aspects through training workshops (Dheda, 2013). During the
training workshops, HCPs were asked whether they had encountered any ADRs in practice
(Dheda, 2013). The HCPs reported that all of them encountered an ADR in practice but that the
chances of them actually reporting it were less than 50% (Dheda, 2013). Dheda (2013) reported
that the spontaneous reporting system showed serious limitations, struggled with under-reporting
and provided poor pharmacovigilance outcomes in South Africa. The poor performance of the
spontaneous reporting system was evident based on the low number of reports received by the
NPC which does not have the capacity to give guidance on all reports received (Dheda, 2013).
Furthermore, the current spontaneous reporting system was never designed to assist in the
management of patients at local clinical settings (Dheda, 2013). What is needed is a more robust
system that can accommodate a rapidly expanding ART programme and integrate
pharmacovigilance activities into the daily clinical operations at primary health care level.
The decentralized system consisted of multidisciplinary teams established at selected clusters (Dheda, 2013). These multidisciplinary team clusters were trained to discuss individual cases and provide treatment options (Dheda, 2013). It was found that this approach increased the number of reports seen at primary health care level (Dheda, 2013). These clusters would still be supported by the NPC through follow-up communications including phone calls, faxes or emails (Dheda, 2013). The NPC would however be required to analyze reports received by the different clusters and provide appropriate feedback on emerging trends (Dheda, 2013).

The successful implementation of the decentralized pharmacovigilance pilot programme in Mpumalanga Province was followed by a roll-out to the North West Province (Siapsprogram.org, 2016). The rollout of the decentralized programme in the North West Province resulted in positive outcomes which include the training of 118 HCPs, the establishment of 20 clusters in 256 health facilities, the use of new, revised ADR forms and the creation of a NPC information bulletin for the North West Province (Siapsprogram.org, 2016).

2.6. Conclusion

Although previous researchers have reported extensively on the phenomenon of under-reporting of ADRs by various HCPs including pharmacists, minimal research was conducted using qualitative methodology, to explore the situation especially in the South African context. It is hoped that this qualitative study will provide an improved understanding of the perceptions and experiences of public sector pharmacists in the South Africa, with the aim of improving the pharmacovigilance system.
CHAPTER 3: METHODOLOGY

3.1. Aim
To investigate the perceptions and experiences of reporting of adverse drug reactions by public sector pharmacists employed in the Cape Winelands District.

3.2. Objectives
1. To explore pharmacists’ perception of their role in reporting ADRs.
2. To describe the knowledge and understanding of pharmacists on the ADR reporting system in Cape Winelands District of the Western Cape Province.
3. To explore the barriers that prevent pharmacists from reporting ADRs.

3.3. Study Design
A qualitative study design was previously used to explore the perceptions and experiences of pharmacists reporting ADRs (Smith, 1998). Since such methods can be effectively used to explore complex practice-orientated phenomena, such as issues related to roles and responsibilities, this approach was followed.

3.4. Sample population, size and procedures
The primary study population consisted of 24 public sector pharmacists in the Cape Winelands District. A purposive sampling methodology was utilized. This method involved the deliberate identification and selection of particular individuals with certain characteristics and experiences and has been described by Smith (1998). In this study 16 pharmacists ranging in gender, age, experience and rank were selected. It was envisaged that they would provide a broad range of perspectives and be the most informative in achieving the objective of the study. Eight pharmacists were supervisor pharmacists while the rest were production pharmacists, including a community service pharmacist and an intern pharmacist. Supervisor pharmacists are more involved with managerial tasks and the attendance of meetings compared to production
pharmacists who focus on patient care and dispensing of medication. Two key stakeholders involved in the Western Cape Pharmacovigilance System were also included in the study.

One of them was a policy specialist pharmacist working at Directorate: Pharmacy Services and primarily involved with the Provincial Pharmacy and Therapeutics Committee. The other, at the time of the study, was the manager of the Medicines Information Centre which forms part of the University of Cape Town’s (UCT) Pharmacology Division. Both were highly experienced pharmacists familiar with the pharmacovigilance system.

It was anticipated that the primary sample size for this study would be between 10 and 16 participants due to the relatively narrow focus of the study. Similar qualitative studies conducted by Elkalmi (2011) and Walji (2011), investigating the under-reporting of ADRs among community service pharmacists, reported a sample size of between 10 and 16 participants (Elkalmi et al, 2011; Walji et al., 2011). Elkalmi et al. (2011) conducted a qualitative study exploring barriers and facilitators amongst community pharmacists reporting ADRs in Malaysia. Walji (2011) conducted a qualitative study amongst community service pharmacists in Canada investigating the pharmacist’s responsibility in reporting natural health product related ADRs.

3.5. Data Collection

Data were collected between August and October 2013 through in-depth interviews using a semi-structured interview guide consisting of open-ended questions (See Appendix 6, page 95). Questions used in the interview guide were initially based on findings in the literature review (Smith, 1998). Open-ended questions encouraged respondents to freely express their views. It was anticipated that initial emerging themes would include workplace barriers to ADR reporting, perceptions of roles and responsibilities towards ADR reporting and awareness of the spontaneous reporting system procedures. Probing questions were used where the interviewers felt that a need existed to clarify some of the participants’ responses. Care was however taken not to ask leading questions by briefing the interviewers beforehand on the dangers of this practice.
The semi-structured interview guide was pre-piloted with one pharmacist who did not form part of the primary study population to identify any potential problems. Although the primary interview guide was not amended, as the interviews were conducted with the participants, the interviewers became more aware of certain recurring themes that made them more sensitive in probing certain responses of participants. The same interview guide was used to interview the key stakeholders, although the probing questions differed with this category of respondents compared with the primary study population.

The assistance of researchers (data collectors) of a local NGO partner, ANOVA, was sourced to conduct the data collection. They were experienced in qualitative research methods. A meeting was conducted beforehand with the two data collectors to brief them on the purpose of the study and to explain the semi-structured interview guide. As the researchers were not pharmacists, time was spent in explaining some pharmacy concepts to them such as patient counselling, the study setting, operational matters and briefing them in the different roles pharmacy personnel play. It was anticipated that the interviews would be conducted in English, as all pharmacists in the study have a good level of English. The data collectors found however that some pharmacists conversed more comfortably in Afrikaans. The data collectors were made aware of this. In practice eight interviews were conducted in English and eight in Afrikaans.

All interviews were tape-recorded by the two independent data collectors using a digital recorder. The data collectors were asked to make field notes recording the additional contextual information such as tone of voice and non-verbal clues. Venues to conduct the interviews were arranged and negotiated with the Department of Health, as it was deemed to be the most convenient for the pharmacists to be interviewed at their place of work. Duration of interviews ranged between 20 minutes and 30 minutes.

### 3.6. Data Analysis

All interviews were transcribed verbatim by the investigator. Data analysis involved categorizing the data into themes using a coding process. Topics from the semi-structured interview guide were initially used as categories for the coding process. The coding framework was organized as
a simplistic, structured Excel spreadsheet. Initial themes used were revised as new topics emerged during the analysis.

3.7. Validity

The validity of the data refers to the extent to which it is an accurate reflection of the phenomena being investigated (Smith, 1998). The topic was explored as far as possible through the use of open-ended questions allowing the direction and the content of the interview to be guided by the interviewer. Here the data could be seen as possessing an ‘inherent’ content validity (Smith, 1998). Respondent validation or “member checking” was conducted during individual interviews to clarify certain points. Here, a respondent’s answers to questions were, in some cases, repeated to encourage clarification by the respondent. Validity was further ensured through the interview of key informants familiar with the reporting process. A clear account of the data collection, analysis and detailed descriptions of parameters has been presented in this research report. This allows readers to judge whether the interpretation of the findings are in line with the data collected and analyzed. In addition, the researcher continuously reflected on the data during the analysis and presentation of the results of the study.

3.8. Limitations

Only 16 pharmacists were interviewed in this study which could be seen as one of its limitations. Whilst this number was in line with participants selected for other qualitative investigations focusing on under-reporting of ADRs by pharmacists, in qualitative research the topic of interest is usually explored until saturation of the data is reached, meaning no new information is forthcoming from the study participants (Elkalmi et al., 2011; Walji et al., 2011). However, in view of the limited scope of the mini-thesis and the narrow focus of the research, this number was determined acceptable.

The investigator is the pharmacy manager of the Cape Winelands District and thus familiar with the study participants. This could be viewed as a potential source of bias that could influence the results obtained. This was overcome by the investigator enlisting the assistance of two data
collectors who had previous qualitative research experience and a basic understanding of the study context. The investigator conducted the interviews with the two key stakeholders, informants. All interviews were tape recorded. The recordings revealed discussions with pharmacists were without fear and restrictions. It appeared that the investigator’s working relationship with the pharmacists, as their district pharmacist, did not negatively influence information shared by the pharmacists interviewed in the study.

The fact that only rural pharmacists were interviewed has an impact on the generalizability of the findings as other HCPs, pharmacist’s assistants, pharmacists and other cadres in the metro districts were not interviewed. Consequently, the findings of this study have relevance to rural pharmacists in this setting but could be applicable to pharmacists in similar rural districts in South Africa.

3.9. Ethics

Ethical approval of the study was received from the University of the Western Cape Senate Research Committee (Registration No: 12/10/31) and permission to conduct it from the Western Cape Department of Health Research Committee (Appendix 7, page 99). Before participating, all respondents were supplied with an information sheet giving detailed information about the study (See Appendix 8, page 100). Thereafter written informed consent was obtained from each respondent participating in the research study (See Appendix 1, page 73). Participants were informed that they could withdraw from the study any time if they felt the need to do so. They were informed that they would not be adversely affected in any way. Information gained in the research study would not be used against them in any way. Confidentiality was maintained at all times and transcripts were stored securely with only the interviewer and primary researcher having access to the transcripts. The findings of the study will be made available to all participants. Information gained from this study will also be made available to the district management of Cape Winelands District, the Western Cape Provincial Pharmacy and Therapeutics Committee and Provincial Pharmacy Services sub-directorate.
CHAPTER 4: RESULTS

4.1. Introduction

The interview respondents consisted of eight supervisor pharmacists and eight production pharmacists. One intern pharmacist and one community service pharmacist were included under the category of production pharmacists. Two key stakeholders who had extensive experience of the pharmacovigilance system in the Western Cape Province were interviewed. Please see Table 1 for additional information including gender, years of service and the institution type where the pharmacists were employed.

Table 1: Demographics of the respondents

<table>
<thead>
<tr>
<th>Pharmacist</th>
<th>Type of Pharmacist</th>
<th>Gender</th>
<th>Years of service</th>
<th>Institution Type</th>
</tr>
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<tr>
<td>SP1</td>
<td>Supervisor</td>
<td>Female</td>
<td>10 years</td>
<td>District Hospital</td>
</tr>
<tr>
<td>SP2</td>
<td>Supervisor</td>
<td>Male</td>
<td>7 years</td>
<td>CDC</td>
</tr>
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</tr>
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<td>Male</td>
<td>21 years</td>
<td>CDC</td>
</tr>
<tr>
<td>SP5</td>
<td>Supervisor</td>
<td>Male</td>
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<td>TB Hospital</td>
</tr>
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<td>13 years</td>
<td>CDC</td>
</tr>
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<td>District Hospital/CDC</td>
</tr>
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<td>8 years</td>
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One of the objectives of the study was to explore pharmacists’ perceptions of their role in the reporting of ADRs. The selection of the supervisor pharmacist category aided the investigation of this objective. One of the themes that surfaced during the exploration of this objective is the pharmacist’s role as gatekeeper and driver of the reporting process. Another theme that emerged was the perception of the importance of ADR reporting.

Another objective was to describe the knowledge and understanding pharmacists have of the reporting process. Two themes that emerged here were the variance in knowledge of the reporting system between supervisor pharmacists and production pharmacists and the under-reporting observed in the system.

As barriers were well described in previous literature, a main objective was to explore the barriers that pharmacists experienced in this specific study setting. A lack of feedback was one of the main barriers associated with this objective.

### 4.2. The role of the pharmacist in ADR reporting

#### 4.2.1. Pharmacists as the gatekeepers and drivers of the reporting process

Pharmacists identified strongly with being the gatekeepers and the drivers of the reporting process. They associated their gate keeping role with being the custodians of medicine and ensuring patient safety with respect to medicines. Their gate-keeping duties included assisting other healthcare workers in the reporting process, such as giving telephonic advice, answering
ADR reporting queries, helping to identify ADRs, ensuring the availability of reporting forms, the collation of forms, making sure the forms were submitted and conducting surveillance on new generic brands. Some pharmacists indicated that the position of the pharmacist in the healthcare delivery chain facilitated their gate keeping duties, particularly the collation and submission of forms. Patients are often seen first by other healthcare professionals before they access their medication at the pharmacy. As the pharmacist is usually the healthcare professional that sees the patient last, the pharmacist has a governance role to reduce possible under-reporting by other healthcare workers.

“So the pharmacist would play a key role, most of the reports that you would get from a patient that experienced an ADR, they would probably come back to the pharmacist because he is the end point, he was the last person to give the medication to the patient, so the pharmacist is key.”

-PP6

Most pharmacists indicated that they felt they should be the drivers of the reporting process.

“Most definitely I think we as pharmacists should take the lead in it... But we should really be the drivers and the force behind it.” – SP2

Creating awareness through regular meeting structures such as the local PTC, clinical M&M meetings and other meetings with the doctors was one way pharmacists proposed that they could drive the reporting process. Pharmacists also mentioned workshops as a means to create awareness. One pharmacist indicated that creating awareness is an on-going process. Another indicated that ADR reporting increases after an awareness event but that it decreases after two months.

“So I think it is important what you say that it is something that is continuous, it is something that flows, if you don’t get the message out...You have to keep momentum...” - SP6

The key stakeholders confirmed that pharmacists have an important role to play. They indicated that pharmacists are the custodians of medicine and should put systems in place to ensure that reporting occurs, motivate other healthcare workers to report suspected ADRs and make sure that healthcare workers have access to the forms.
“I think the role of the pharmacist is to encourage other people to report, to create awareness of the actual harms that medicines can cause.” - K2

4.2.2. The responsibility of the pharmacist in reporting ADRs

Pharmacists indicated that they are responsible for the reporting of ADRs because they are the custodians of medicines. They believed that they are responsible for promoting and encouraging ADR reporting because better reporting would improve the safety of medication. Some pharmacists indicated that they should conduct surveillance on new generic brands of medication to ensure the patients’ safety. They mentioned that new generic brands of medication could have quality issues that should be detected by pharmacists.

“...but some people experience more adverse effects with especially if you changed the brand...” - SP2

Pharmacists spoke of their pharmaceutical care role and their capability in reporting ADRs. One pharmacist indicated that counselling of patients about their medication needs is part of the pharmacist’s pharmaceutical care role.

“...depending on the severity of it, we would counsel the patient and tell him next time he sees the doctor he needs to report the ADR, so that the doctor is aware of it. If it is so severe that he is not going to take his medication then obviously you have to step in straight away.” - PP5

Through counselling sessions, the patient has an opportunity to disclose to the pharmacist about a potential ADR that the patient may be experiencing. However, in practice, pharmacists would rarely report an ADR from evidence obtained in a counselling session but would usually refer the patient to the medical officer.

Two pharmacists remarked that in the past, patients were not sensitised to possible side-effects and ADRs that they might experience, for fear that they might over-report the reactions.

“...but we don’t talk to patients a lot about side-effects, because we are afraid that they would think that they do have side-effects...” - SP6
Some pharmacists indicated that they are aware that when the branding of a medicine changes, this may have a psychological effect on the patient who may then report that the medication has a different effect than before.

“Sometimes a patient might look at a pill that is yellow, and it used to be green and now it suddenly does not work, then I would be unsure about it, is it in his head or is it really the case. It can be that it might not work, so you have to keep your eye on it.” – SP3

Pharmacists had varied opinions about whether they felt capable to report and identify ADRs.

“...yes. I feel capable.” – SP4

“...No I don’t feel ... I think the problem might be the working conditions under which people are operating nowadays.” – SP8

From what pharmacists reported, it seems that most potential ADRs are identified by pharmacy staff reading patient folders. Doctors’ notes in the folders often provide clues about whether a patient experienced an ADR or when a patient’s medication was changed. Pharmacists would then report an ADR directly from the doctor’s notes.

“... I filled in the form according to his notes...”- PP8

The key stakeholders reported that pharmacists should play the gatekeeper role and enable other healthcare workers to report ADRs and not report themselves. One key stakeholder respondent left the door open for pharmacists to report only from the doctor’s notes. The other key stakeholder had the opinion that pharmacists should only perform the gate-keeping duty as they do not have the capacity or the clinical knowledge and should therefore not conduct direct reporting of ADRs.

“The pharmacist should maybe be the one that keep the forms and make sure that people fills them in and sends them on but I do not think they should actually be filling in the form, I think the nurse or the doctor who has the patient in front of them should possible be filling in the form.” – K2
“I know it is supposed to be the pharmacist’s role to report and to fill in the forms, but actually they do not actually see the patient and the form requires you to actually have some clinical knowledge of the patient.” - K2

“… then they can investigate further but in this point in time they do not have the capacity, or the ability or the situation to do that kind of work, so maybe just as a gatekeeper.” - K1

“… but I don’t think they will pick it up with a patient, because they don’t talk to a patient, but they can pick it up in folder.” - K1

Interestingly, the intern pharmacist remarked that the responsibility to report ADRs might stem from the fact that pharmacists studied pharmacovigilance as part of their curriculum. The intern pharmacist questioned whether pharmacovigilance was part of the doctors training curriculum.

“Yes, especially the pharmacovigilance aspect, because that is something that you study at university. I am not sure if the doctors have pharmacovigilance as a topic, do they cover it, and I know I covered it so that is why I feel I have got a responsibility,…” - PP8

Some pharmacists indicated that a pharmacist can’t really report an ADR because only the medical officer has the authority to change a patient’s prescription. One pharmacist reported that ADRs cannot be identified merely through observations and patient counselling. Only through clinical tests and thorough examination of the patient can one identify an ADR and this does not form part of the scope of practice of a pharmacist.

“Sometimes you would see a reaction but then you would send the patient back, because you can’t just speculate, you can’t pin point something if you have not done a blood test or something. So in most cases you would refer the patient back to the doctor.” - PP7

According to some pharmacists, patients should only report ADRs to the medical officers. This belief may explain why patients are referred back to the medical officer if they expressed a problem at the pharmacy. Some pharmacists indicated that when patients report ADRs to the pharmacists they are asked why they did not report it to the medical officers in the first place. One pharmacist indicated that even if they do report an ADR, they must still send the patient back to the medical officer to change the prescription.
“Now they come to us and then we can’t change a prescription, because that is why I feel that the responsibility lies with the doctor…” - PP4

This contrasted starkly with the role of the pharmacist as reported by the intern pharmacist. The intern pharmacist believed that the role of the pharmacist should include identification of ADRs.

“Basically it is to identify or being able to identify ADRs. And then also its cause, and taking into account which different medications could have caused it…” - PP8
4.2.3. The responsibility of other healthcare workers

Although pharmacists mentioned that they play a key role in the reporting process, they remarked that other healthcare cadres should also take responsibility for contributing to the reporting of ADRs. Various comments were made about the role medical officers and nursing staff play and how they contribute to the reporting process and the barriers that they experience. Most pharmacists indicated that it is a shared responsibility although the roles between the healthcare professionals differed.

“Ok, the responsibility is with everybody, I think so...” -PP2

The relationship and communication between the pharmacist and medical officers and nursing staff became evident through their comments. Some pharmacists mentioned that medical officers might be in a better position than pharmacists to report on ADRs because their consultation rooms are more private compared to the hatch at the pharmacy where the pharmacists have their interactions with the patients. On the other hand, some pharmacists had the view that medical officers are perceived as being very busy and that they do not have the time to report on ADRs.

“No, what could maybe put the doctors off is that it might be time consuming to fill in the form, they are very busy and must see a lot of patients, and then they still have to fill in an ADR...”- SP2

Some pharmacists indicated that medical officers and nurses reported more ADRs than pharmacists. Although they reported more it was the view of some of the pharmacists, that medical officers were not always sure what to report on. They tended not to report common ADRs.

“So stuff like that must be conveyed to the doctors that it is not only the serious reactions that need to be reported but the more common and minor reactions must be reported too.” – SP5

Some pharmacists also indicated that medical officers might be quicker to connect a certain ADR with a specific medication compared to pharmacists.
“I think, and this might be only my perception, but that the pharmacy might be more careful to say that a certain medication is the cause of an ADR, whereas a doctor would be quicker to say it is because of a medication, they are quick to put the fault at the medication’s door.” - SP6

Some pharmacists indicated that they had good cooperation with the medical officers. In some cases, the communication between the pharmacy staff and medical officers and nursing staff could be improved upon.

“‘Yes, we have good cooperation and for the last two years, we have created more awareness, we have started through our PTC to give feedback.’” – SP6

“‘Doctors have more time and it is more private, patients would not be so open, if they can talk to the doctor behind closed doors.’”-SP4

Interestingly, some pharmacists indicated that the responsibility depended on which healthcare professional the patient saw in the healthcare delivery chain and who the patient informed about the ADR experienced. One pharmacist indicated that the responsibility depended on who the patient informed. Another pharmacist indicated that the responsibility lies with the pharmacist because it is the pharmacist who sees the patient last. Patients that came back monthly to collect their medication would see the pharmacist and not the other healthcare professionals. The pharmacist may therefore be responsible to report any ADRs that the patient might complain of.

“‘Well it is because you are basically the last person the patient sees and you have a responsibility if they come back to you because they might only experience the reaction in a month’s time, when they collect their second prescription.’” -PP8

Some pharmacists indicated that patients are sometimes afraid to consult the doctor or the pharmacist.

“I would think that the patient would complain first at the doctor. They complain at the pharmacy too, sometimes we find that they are afraid of the doctors, so they would rather come to the pharmacy and talk to the pharmacy staff.” – SP3

It is evident that a complex relationship exists between the pharmacists and medical officers and nursing staff. Pharmacists refer patients back to the doctor for various reasons linked to the
reporting process and this action forms part of the role of the pharmacist as facilitator of the ADR reporting process in an attempt to decrease under reporting. This will be explored in more detail later in this section. Time constraints and work load pressures of the pharmacist serve as another motivator for the pharmacist to refer the patients back to the doctor. The pharmacist is thus involved in the identification of a potential ADR reporting opportunity compared to the actual reporting of ADRs.

4.3. Importance of reporting

4.3.1. Pharmacists view ADR reporting as important

All pharmacists confirmed that the reporting of ADRs is an important process. The reasons include that it is in the interest of the patient’s safety, it has an impact on guidelines and policy, it is part of their role in surveillance with regards to medicine safety and that serious reactions can lead to the death of patients.

“...look it is important, the main function is to make it as safe for the patients as possible. There are different reasons for ADRs to take place.” - PP6

“If it has a significant impact on the quality of life of the patient.” - SP4

“Yes. Yes, of course it is important because I think sometimes we take for granted, the drug has been available for a long time and surely, everybody knows about the ADR events, but no one actually reports it, so it is important that you do.” – SP1

4.3.2. ADR reporting can contribute to patients’ safety

One pharmacist indicated that it is important to record ADRs to stop problematic medication and replace it with safer medication. In order for this to happen there should be substantial reporting of a specific problematic drug. An example that was given was enalapril, an anti-hypertension medication which causes coughing as a side-effect and affects a large number of people. One pharmacist indicated that ADR reporting was part of setting up a safety profile of the product and that it could even affect the scheduling of the product. The intern pharmacist indicated that it is important to report in order to assess the risk: benefit ratio of the medication. Some pharmacists
believe that if a medication is found to be responsible for a large number of ADRs, it could lead to its withdrawal from the market.

“Yes, it is very important. Like I said before, if everyone reported it, then the drugs that give a lot of problems, the frequency of the ADRs of a specific drug, will be noticed if everyone reports on it, but if everyone does not report on it then, then it will slip through.” – SP5

“...if you get a drug reaction with one drug, then you can remove that drug, and substitute it with a more modern drug, that has fewer drug reactions and fewer effects of people.” – PP1

“Yes, basically what are the chances of the medication causing more harm than good, so you have to keep track of that, because it can be withdrawn from the market if it causes a lot of adverse reactions.” – PP8

4.4. Familiarity of the ADR reporting process

4.4.1. Understanding the reporting process

Most supervisor pharmacists could describe how the reporting process works and could indicate what role they play in the reporting chain. Most indicated that they were involved in the collation of the reporting forms which were then submitted to the district office. From there the forms were forwarded to the Medicine Information Centre (MIC) and Medicine Control Council (MCC). The key stakeholders confirmed that a circular and posters were recently issued by the Department of Health that aimed to explain the reporting process.

Production pharmacists were not always sure about how the reporting process worked in their area. One pharmacist indicated that at their facility reporting forms were sent to the sub district office whereas at other facilities the reporting forms were sent to the pharmacy which forward the forms to the district office. Uncertainty was also expressed with regards to where the forms were sent after being collated by the pharmacy. One pharmacist indicated that she had never received a reference number in five years of reporting ADRs. Most production pharmacists indicated that the reporting forms are collated by the supervisor pharmacist. Knowledge of the reporting process seemed more elementary amongst the production pharmacists compared to the supervisor pharmacists. The community service pharmacist and the intern pharmacist had a good understanding of the reporting process compared to other production pharmacists.
“There is an ADR form, that is filled in, and that is sent to, I am not sure who it is sent to, but all the ADRs are sent to a central person or whatever.” – PP2

“So from last year it is sent to the district office, pharmaceutical services, so they get the whole district’s ADRs and then they know what is happening in the district, so they can also push it from their side.” – SP5

4.4.2. Reporting as a continuous reporting process

Some pharmacists indicated that most of the time reporting is an on-going process and reports are submitted as soon as they are received. One pharmacist indicated that it is arguably better to collate all the forms and send them away at the end of the month although serious reactions need to be reported immediately. One pharmacist indicated that continuous reporting depended on how busy the pharmacy is. When the pharmacy is very busy it is sometimes easier to make a note of the ADR in the folder and only report it at a later time.

“I think it is an on-going process but it would be much better to send everything at the end of the month together, but a very serious drug reaction, something that can affect the liver or the kidneys, then it must be reported immediately in order to take it off the shelf.” – PP1

4.5. Under-reporting of ADRs

The study revealed that under-reporting amongst healthcare practitioners does take place. It was reported that common ADRs are often under-reported. Furthermore, identification of ADRs was not always found to be straightforward which also contributes to the phenomenon of under-reporting. It was evident from pharmacists’ comments that they do play a role in decreasing the under-reporting of other healthcare workers. Some pharmacists noted that although under-reporting does take place in practice, cases where healthcare workers sometimes over-report are also possible. A key stakeholder reported that some specialists target reporting certain medications in order to raise question marks about their safety in the hope of them being removed from the list of medicines available in the province.

“...at that one meeting they mentioned that they would like the second generation anti-psychotics, so they said well then we should report on the side effects of the first generation anti-psychotics. So is there suddenly going to be a spike, then people will think oops!” – K1
4.5.1. Under-reporting of common ADRs

Most pharmacists indicated that common and known ADRs should be routinely reported. One pharmacist indicated that it remains important to continue reporting ADRs even if they are commonly reported. Another pharmacist indicated that ADRs become more common as the years go by thus it is important to identify ADRs in the first couple of years of a medication’s launch. Some pharmacists remarked that common ADRs are not recorded as they should be. They reported that medical officers might not report on common ADRs.

*The doctors do not always have a good perception of what to report...*”– SP4

“Well the most common one’s that you see regularly, for example the enalapril one that people do not record anymore”...”– SP1

“I think it is important to report common and uncommon reports...does not matter what reactions, all reactions must be reported so that is important yes.”– PP1

Common ADRs might be easier to record but some healthcare professionals fail to see the importance of recording these common ADRs. If the suspected ADR is already included in a package insert then healthcare workers might be reluctant to report it.

Some pharmacists had the opinion that rare ADRs might be easier to identify. One pharmacist indicated that severe ADRs would be dealt with promptly. The pharmacist reported that the very severe cases might not be seen in the primary healthcare clinics but in provincial hospitals.

*So sometime I feel that some of these reactions are severe enough to report or you get it so many times for the same drug for different patients but I myself as a pharmacist feel that I must fill out a ADR form, for every or all the reactions and not only for the ones that is stipulated on the patient information leaflet.”* – SP7

One pharmacist mentioned a circular that was issued by the Department of Health that recommends that only reactions that are not known or listed on the package insert should be reported. This differs from the common view held by most pharmacists that everything should be reported.
“The doctors do not always have a good perception of what to report, lots of times, there is this one drug that causes people to cough a lot, then they say it is so common, why must we report, everyone knows about it, why must we report, it is just another form that must be filled in.” -SP3

One key stakeholder stated that healthcare workers are not always sure when to report ADRs. Common ADRs are not reported but the unusual and more interesting ADRs are more readily reported. Under-reporting of common ADRs thus occurs because healthcare workers are not sure if they should report on those reactions.

“Ya, I think what makes it also difficult is they do not know when they should report an ADR, it is a common thing they tend to not report it, if it is unusual they will report it, if it is something interesting then they will report it, but I think in most cases ADRS are not reported because I think healthcare workers are unsure when to report and when not to.” -K1

One key stakeholder was of the opinion that ADRs associated with new medication on the market and unexpected and serious reactions should be reported, rather than minor and common ADRs. The stakeholder mentioned that the Medicine Information Centre (MIC) has developed a poster with information about what should be reported.

“I don’t think people should be reporting absolutely everything. They should be selective.” –K2

One pharmacist indicated that ADR reporting might not be seen as a priority and has to compete with other work processes. Under-reporting might also be due to ADRs that are seen as not serious enough to report. A key stakeholder confirmed this by saying that ADR reporting is not considered important enough due to the fact that no-one acts on it unless there is a major consequence. There is no immediate response to an ADR report. Clinicians do not report as they should because they do not get feedback.

4.5.2. Difficulty in identifying ADRs

Some pharmacists reported on the difficulty in distinguishing between a side-effect, ADRs and allergic reactions which the patient may experience. One of the pharmacists argued that there is a need to define properly what an ADR really is.
“...but if you get an ADR I think it is more something that is not known as a side-effect, and that is actually more serious, that is my perception, there is a very vague line between the two.” - PP2

Common ADRs can be easier to identify compared to more complex ADRs.

“...for example the enalapril, you know what to look for, it is easy to identify but with more complex stuff if you are not sure if it is the disease, then it is a bit a difficult.” - PP8

Some pharmacists had the opinion that other factors could be the reason for the perceived effect experienced and not the medication, such as the underlying disease of the patients. Although some pharmacists reported that those ADRs they can identify from the medical officer’s notes in the patient file they tend to report. One pharmacist however did indicate that one could still struggle to pick up the ADR from the medical officer’s notes. This was because it is sometimes difficult to distinguish between an ADR and the patient’s disease. This could also mean that in some cases an ADR could only be picked up from the doctor’s notes months after the occurrence, resulting in a delayed report.

Natural remedies and food could also potentially cause a reaction that could be mistakenly linked to a medication.

“...there are so many factors, you can’t always say it is that...maybe the patient took it with something else, something at home that was not even prescribed, a lot of patients use natural remedies.” - PP6

“There are listed side effects...you have to get a ‘nose’ for it, it is very unscientific, if the patient really complains about it and it is a bit over the top then you would send him/her to the doctor to check and ask if it is a side effect or not...” - SP3

“...it is not necessarily that that medication gave you the reaction, you might blame the medication for something that you experience...” - SP6

Most pharmacists felt unsure about the identification of ADRs in the field. This insecurity about what could be the possible cause of an ADR led to the practice of referring patients back to the medical officer in order to gain clarity about the identification of the ADR and their possible
causes.

“But the way I see it you cannot pinpoint something that you only see, that is just speculation, you have to send the patient back to the doctor to do the tests, and then the final report is just passed on...” - PP7

The study revealed that pharmacists associated an ADR with an intervention that must take place with regards to the therapy of the patient. This could include changing the dose of the medication, stopping the suspected medication and/or prescribing another medication. One pharmacist indicated that the medical officers might just lower the dosage of a medication suspected of causing an ADR, in response to an ADR experienced. This adds to the motivation for referring patients to the medical officer in order to address the required therapeutic intervention. Not only are patients referred to the medical officer to make sure about the cause of the suspected ADR, but also to amend the therapy of the patient in response to the ADR experienced. One pharmacist indicated that most of the time it is the medical officer’s decision whether it is an ADR or not.

“Usually they would stop the medication if they feel that it is giving them a problem usually they stop the medication, so did it improve after stopping the medication?” - PP6

“...the patient went to the doctor and the doctor said it could be one of these three medications, the dose was changed (amlodipine one two times a day) and it still did not solve the problem, the doctor actually wrote a long what-to-do for the next three months so whoever the patient came to see ok next month try maybe this...” - PP3

Some pharmacists reported that the long list of medication that patients sometimes take add to the complexity of identifying which medication might be responsible for the ADR.

“...so it is a lot of medications that patients are on, and you cannot always identify what medications caused it...because they use so much medications at the same time...” - SP4

One key stakeholder indicated that public sector pharmacists should just report on any medications they suspect and should not spend time trying to pin-point which medication is responsible. It was the key stakeholder’s view that the identification of ADRs should be left to
the MIC. Public sector pharmacists do not have the resources to routinely identify which medications could be responsible for the suspected ADRs. The key stakeholder reported that it sometimes takes the MIC more than two hours to find out which medication is responsible.

4.5.3. Over reporting of ADRs

Although most pharmacists indicated that under-reporting occurs, some have, however, alluded to instances where over-reporting might also take place. One pharmacist indicated that pharmacy staff is more likely to report a medicine that was not liked. A key stakeholder confirmed that clinicians might try to get rid of an unwanted medication through reporting suspected ADRs caused by the drug.

“... at that one meeting they mentioned that they would like the second generation anti-psychotics so they said well then we should report on the side-effects of the first generation anti-psychotics. So is there suddenly going to be a spike in then people will think oops!” -K1

Another pharmacist indicated that more reports were usually submitted from nursing staff during a vaccination campaign. This can be attributed to nursing staff being sensitised in training workshops before the scheduled vaccine campaign to be on the look-out for any reaction.

One pharmacist asked whether an over-expectation existed with regards to ADRs reported. Another pharmacist indicated however that ADR reporting is a very uncommon process that one might see every six months.

“Then I just want to add, sometimes there is too huge an expectation of ADRs then there would really be out there, they expect 2000 ADRs to be reported but in reality there might only be 300.” -SP3

Another pharmacist however indicated that medical officers seemed to have an incentive to report although the pharmacist was not entirely sure what it could be. One possible reason offered was that medical officers had access to otherwise restricted medication after the report had been completed.
“The doctors like I said to you are now a lot more willing to fill in the forms. And I think their motivation is that they can prescribe things like second line drugs, because they have filled in a motivation, so there is an incentive there for them to do it.” - PP4

4.6. Perceived barriers

Pharmacists identified barriers that made it difficult to partake in ADR reporting. Various barriers were mentioned including no privacy at the hatch when counselling patients, time constraints, workload pressure, lack of feedback, the long list of chronic medications that patients are on, limited contact time with patients, issues surrounding the reporting form, poor communication between healthcare workers and language barriers between the pharmacists and the patients.

The main barriers experienced by most of the pharmacists are a lack of feedback, issues surrounding the reporting form and workload pressures and time constraints.

4.6.1. Lack of feedback

Most pharmacists remarked that they did not receive feedback on reports submitted. One pharmacist added to this by saying that no feedback is provided on what was done to rectify problems caused by ADRs.

Some pharmacists however did receive feedback. Feedback provided included the district office providing feedback every quarter on the number of ADRs that were reported, feedback being provided at the District PTC and feedback received from the provincial HAST department on the number of ADRs caused by ARV medications. Three pharmacists indicated that they do provide feedback to their prescribers. Two pharmacists mentioned that they provide feedback at their local PTC meeting. One pharmacist lamented that the MCC should provide better feedback but did however acknowledge that the MCC does from time to time send medicine information warning letters to medical officers and pharmacists. The intern pharmacist indicated that they did not receive any feedback on the forms submitted and there was uncertainty whether the authorities received the reports.

The type of feedback that some pharmacists would want to receive ranged from basic information such as common ADRs that were reported, to more comprehensive information such
as the consequences of the ADRs reported. Pharmacists regarded receiving feedback as an early warning about medication that could potentially be problematic. Pharmacists need to have access to the information in order to counsel patients better.

One pharmacist indicated that feedback is seen as a sign that the reporting of ADRs is not considered to be a waste of time. Improving the feedback provided to HCPs would also help in promoting ADR reporting amongst them. Another pharmacist and one key stakeholder indicated that reporting of ADRs, seen in the absence of feedback, is actually surprising.

“...and feedback, that is also done in the correct manner, that people does not feel that yes, I report but people does not do anything about it, so what...” - SP5

“It is easy to fill in a form but if do not get a response then people are going to lose interest...” - SP2

A key stakeholder mentioned that there are various viewpoints as to what constitutes feedback and whether it is deemed adequate by the person reporting the ADR. According to this stakeholder, lack of feedback should not be offered as an excuse for under-reporting and a “Dear Doctor” letter (medicine warning letter) should be acknowledged by HCPs as a form of feedback.

“My thing is that when you get a “Dear Doctor” letter, that is because of an ADR. And that is the feedback.” - K1

Another key stakeholder indicated that HCPs required immediate feedback and that the “Dear Doctor” letter might reach HCPs too late to be considered adequate feedback.

“But is almost too late feedback to me that. People should know about it before you get that dear doctor’s letter.” - K2

### 4.6.2. Issues surrounding the reporting process

Barriers in this category are associated with the reporting system itself that is perceived as being too complicated, the complexity of the reporting form, the availability of the reporting form and the awareness and understanding of the reporting process.
There were conflicting reports on the complexity of the reporting process. Some pharmacists indicated that the reporting process was easy and simplistic while others indicated that the reporting process was too complicated and acts as a barrier. One pharmacist reported that the reporting process differs between facilities while another indicated that the reporting pathway is too long. They expressed a need for the reporting process to be standardised and be made more simplistic.

Most pharmacists indicated that the availability of the reporting forms is not a problem and that HCPs should have adequate access to the reporting form. Most healthcare workers would obtain master copies from their local pharmacy either electronically or in hard copy format. Some pharmacists mentioned that a master reporting form can also be found in the South African Medicine Formulary, implying that it should be readily available.

Some pharmacists expressed a need for the reporting form to be standardised. They indicated that different forms exist for ARV and TB medications, other medications and vaccines.

“I know you get different forms for vaccines, ARV’s and normal adverse drug reactions.”-PP3

There were conflicting reports on the time taken to complete the reporting forms and the complexity of the forms. Some pharmacists indicated that the reporting is easy and simplistic and it takes very little time to complete the form. Other pharmacists reported the opposite, indicating that the form requires information that is not always available to them and that the form is complex and takes considerable time to complete. Some pharmacists indicated that they struggle with the section that requires that sequelae of the suspected ADR be recorded because this information is not always available to the healthcare workers. One pharmacist indicated that there is limited space on the reporting form to record all suspected medication. The pharmacists mentioned that not all medications can be recorded in some cases.

“...because some of those questions about the consequences, it is more clinical, that the pharmacy staff might not know, and if we can’t get the information from the notes then, we don’t always have the information to help us fill it in...”- SP6

One of the pharmacists indicated that the reporting form was recently updated which makes it easier to complete. The stakeholder confirmed that the Medicine Information Centre consulted
role-players when they designed the new form. Tick boxes were added to make it easier to complete. The key stakeholder confirmed however that pharmacists might not always have access to all the information needed to complete the reporting form.

The pharmacist indicated that sometimes the fax lines to NADMC were busy while trying to submit the report.

“All the doctors have with them Adverse Drug Reaction forms and it really is very quick, you just stick on a label, you just write all the…it is not a long form or anything.” –PP3

4.6.3. Workload as a barrier

Most pharmacists indicated that time constraints and workload pressures make it difficult to report ADRs. In the busy state setup, healthcare workers are faced with different priorities and reporting of ADRs has to compete with other working priorities. Pharmacists indicated that medical officers and nursing staff have other forms to complete and ADR reporting adds to the paperwork burden. As reported earlier, some pharmacists see the reporting form as difficult to complete and takes time to complete. One pharmacist indicated that although reporting is straightforward they tend to neglect it whenever they are busy and have to work overtime.

Some pharmacists however indicated that workload pressures is not really a contributing factor to under-reporting as reporting is a straight forward process. Both stakeholders confirmed that workload pressures and time constraints are barriers that prevent healthcare workers from reporting as they should.

“Sometimes I can’t really be sure that it is an ADR, but I fill in the form anyway, I decide if it is an ADR or not, but time is a factor...” -SP6

“I think if you take the doctors working in the hospital, its time because they need time to fill out the form, and they need the right information like all the medication that the patients were taking...” -SP7

“...I know it is only one form but I have 100 patients needs that I have to attend to...I know it only takes a 20 – 30 minutes, but in that amount of time I can do a lot of other things...” -PP1
“So that is the biggest problem, lack of staff, it is not because of not wanting to, it is about prioritizing, it’s a huge thing…” PP5

“Huge role, huge role. I think it is the workload.” - K1

“I just feel that they do not have the time to do it, they just want to get through the patients...if it comes to 16h00, people just go home...they are not in the mood for such things.” PP7

4.6.4. Lack of privacy

Two pharmacists mentioned a lack of privacy at the dispensing hatch as a barrier, when counselling patients, compared to medical officers who usually see patients in consultation rooms. One pharmacist alluded to the fact that patients might be more inclined to disclose to the medical officer whether they had experienced an ADR because of the private setting compared to the pharmacy.

“...because at the hatch there is no real privacy for the patient, but in this pharmacy they are busy renovating...” - SP2

“Doctors have more time and it is more private, patients would not be so open, if they can talk to the doctor behind closed doors...” - SP4

4.6.5. Limited contact with patients

A hospital pharmacist mentioned the lack of contact with patients due to the majority of their workload consisting of in-patient dispensing.

“But here by us we do not have direct communication with the patient. So the doctor or the sister will report, here by us the doctor would report more, and we send it away.” - SP5

4.6.6. Language barriers

One pharmacist indicated that patients speaking a different language might make reporting a problem.

“I can’t speak Xhosa, sometimes the patient would tell you in Xhosa what the problem is, everybody in the pharmacy might not know how important that is and what it is.” - PP3
“\textit{I think sometimes we have English speaking doctors here, and our community is Afrikaans speaking, this might be a barrier too...}” - SP4

4.7. Facilitation measures

Various methods to aid the reporting process were mentioned by the pharmacists. These include the use of technology and electronic reporting, creating awareness through dedicated workshops and through PTCs, visual aids like posters, continuous training, and more staff to reduce the workload, the use of an acknowledgement letter after reporting and better feedback.

4.7.1. Creating awareness

Some pharmacists indicated that better awareness is needed amongst healthcare workers and patients to improve the reporting process. Improved awareness can be brought about through discussions at the PTC meeting, training workshops and the use of visual aids such as posters. Posters can sensitise patients about the existence of ADRs and inform healthcare workers on how the reporting process works. One pharmacist mentioned that new staff members should be informed about the reporting process and that supervisor pharmacists should encourage their staff to report more, especially pharmacist’s assistants. Although pharmacist’s assistants might feel out of their depth when it comes to ADR reporting, through encouragement and mentoring however, they can contribute to the reporting process.

A key stakeholder confirmed that increased awareness can be created by putting up posters to remind people to report ADRs and through discussions at PTC level. The key respondent continued to say that pharmacists should be informed to look in the folders of patients and scan for suspected ADRs experienced by the patient.

The other key stakeholder mentioned that there should be a reporting form in every folder to serve as a reminder to people to report ADRs.

\textit{“...if there were visual aids like a poster to help show what a drug report is, put up the poster, they would walk everyday alongside the poster, and they would get to know the process, the poster needs to show the process that must be followed, so it must just get easier, and the contact numbers must also be on the poster.”} - PP1
“We just keep on informing the doctors about the importance thereof, at meetings, or on a personal level, doctors are not always aware of the form, we ask if they have enough forms, if we must give them more forms…” - SP4

“No I feel everybody is aware of how to do it… a lot of emphasis have been put on it… everyone is informed about it, at PTC level it is mentioned regularly” - PP6

4.7.2. Facilitation of the reporting process

Some pharmacists indicated that the reporting form should be made more available and that the reporting form needs to be simplified. One pharmacist made the recommendation to allow the doctor and the pharmacist to complete two halves of the form.

“The form must be made available as much as possible.” - PP6

“…maybe there should be a thing introduced where the doctor would say half fill out a form to report an ADR” – PP2

A key stakeholder reported that ADR reporting forms must be made more accessible. The key stakeholder continued to say that the reporting form was recently updated and made easier to complete. The stakeholder did however mention that the reporting form could be made even simpler and streamlined by removing the product complaint section of the reporting template.

“I mean we try to get a lot of input when we designed it and we tried to keep on updating it and we only added the TB drugs quite recently and the tick boxes for the TB drugs. But there is sort of essential information that we have to have.” - K2

4.7.3. Improving feedback

Improved feedback was mentioned by some pharmacists as a necessity for improving reporting of ADRs. One pharmacist commented on the type of feedback that needs to be improved. The suggestion was that the feedback includes the percentage of ADRs caused by a specific medication. One pharmacist proposed that at a when a certain percentage of patients experience ADRs for a particular medication then that medication should be deemed undesirable and be removed from being available to the public. One pharmacist indicated that better feedback can be
provided to prescribers at the PTC meeting. Another pharmacist indicated that an acknowledgment letter would be accepted as feedback.

The stakeholders confirmed that feedback is an area that needs improvement. Improved feedback will increase reporting by creating awareness that will keep the reporting process alive.

“Yes, an acknowledgement letter, yes, yes...” - SP4

“...but what I think will change reporting is that they are given feedback which will keep them aware of the problem, or keep them aware that they have to report, keeping the awareness alive, so the feedback will maybe cause it to increase.” - S1

4.7.4. Electronic reporting

Some pharmacists indicated that electronic reporting might be the answer in improving the reporting process. One of these pharmacists questioned however whether it would be better than the current paper-based reporting process. She argued that ADR reporting should rather be made part of general work processes. Electronic aids like smart-phone applications can also assist pharmacists in providing the necessary information that can facilitate the reporting process.

A key stakeholder confirmed that electronic reporting could make it easier to report but wondered whether the necessary electronic infrastructure such as an adequate number of computers at facilities is in place.

“That is a difficult answer...maybe incorporate technology...we are still very paper based.” – SP1

“I am not sure if an electronic system where you get immediate feedback, if you click then it would say there has already been reported 100 today, I don’t know and I have doubt that if we don’t do it on paper then we will not do it on a computer, I am not sure, but if it can become more part of the work process then it might make it easier...” - SP6

“...it is impossible to know every single ADR. We need smart phones and APPs that goes with smart phones because if you are not going to get it computerised we need something that is accessible to us.” - PP5
“I think it would be really nice to have a computer with your patients’ details on to be able to click on a box that says Adverse Drug Event.” - S2

4.7.5. Other facilitation measures

One pharmacist indicated that ADR reporting has already been incorporated into the performance evaluation of staff members. The pharmacist also mentioned providing recognition at the PTC to those healthcare workers that reported in the specific time-period. This created awareness amongst the medical officers as well as creating a competitive culture amongst the prescribers to aid the reporting of more ADRs. Another pharmacist remarked that a culture of reporting should be established if one would hope to improve the reporting of ADRs. One of the key stakeholders confirmed that reporting should become part of staff members’ performance evaluations and should be measurable, keeping staff members accountable to report ADRs.

“There is not a culture...so they should develop a culture so that everybody see the importance of it and develop the importance of it, drug reaction reporting” - PP8

Another pharmacist indicated that the working relationship between the doctors and the pharmacy should improve. It should also be clear whose responsibility it is to report ADRs between the doctors and pharmacist, another pharmacist remarked.

One of the pharmacists confirmed that although the new pharmacovigilance circular issued will make the process clearer, it will not necessarily lead to better reporting. What is really needed is improved feedback to HCPs. Another key stakeholder indicated what really is needed to improve reporting is for reporters of ADRs to know that the reporting resulted in an action or outcome. The stakeholder felt that forced reporting, as seen in KwaZulu-Natal, is not the answer.

4.8. Conclusion

The findings of the study provide insight into the role, duties and responsibilities of the pharmacists in relation to the pharmacovigilance reporting system as well as the complex relationship that exists between pharmacists and other HCPs. Knowledge was also gained about the perceptions and experiences of pharmacists, the barriers they experienced and the measures they propose for improving the reporting process.
CHAPTER 5: DISCUSSION

5.1. Introduction

The study highlighted five major findings, which gives us an understanding of pharmacists’ perception of their roles and experiences of reporting ADRs in the Cape Winelands District. These will be discussed in this chapter. Firstly, pharmacists acknowledge the importance of ADR reporting, but seldom report ADRs themselves. Secondly, pharmacists identify ADR reporting opportunities and enable other HCPs to report ADRs. Thirdly, pharmacists associate an ADR with a therapeutic or clinical intervention. Furthermore, pharmacists feel that common ADRs should be reported and not only serious or rare ADRs. Various means of facilitating the reporting of ADRs were recommended by pharmacists. Lastly, pharmacists gave various reasons for the under-reporting of ADRs and the barriers experienced.

5.2. Importance of ADR reporting

Pharmacists in the study strongly acknowledged the importance of ADR reporting. This could be attributed to pharmacists seeing themselves as the custodians of medication (Pharmcouncil.co.za, 2015). Pharmacists in the study associated the reporting of ADRs with medication safety and felt responsible for ensuring it. In spite of this acknowledgement of the importance of ADR reporting, pharmacists rarely reported an ADR themselves. Pharmacists, like other HCPs, reported that they encountered ADRs in practice every day. Nevertheless they were reluctant to report ADRs. This phenomenon of pharmacists acknowledging the importance of ADRs but not necessarily reporting them is consistent with international literature (Suyagh et al., 2015; Jose et al., 2014; Ahmad et al., 2013; Walji et al., 2011; Elkalmi et al., 2011, Green et al., 2001)

According to Elkalmi et al. (2011), who carried out a qualitative study exploring barriers and facilitators amongst community pharmacists reporting ADRs in Malaysia, although pharmacists generally exhibited a positive attitude when it came to pharmacovigilance, the respondents in
that study rarely reported ADRs themselves. Similarly, Walji et al. (2011) conducted a qualitative study amongst community service pharmacists in Canada investigating the pharmacist’s responsibility in reporting natural health product related ADRs found that they seldom reported ADRs although they acknowledged that this falls in their scope of clinical responsibility and was important (Walji et al., 2011). In the South African context, Dheda (2013) reported on the implementation of a pilot patient centered decentralized pharmacovigilance system in Mpumalanga, South Africa. The training workshop that formed part of this programme revealed that all HCPs had encountered one or more ADRs before but fewer than half of those ADRs were reported (Dheda, 2013).

Pharmacists’ acknowledgement of the importance of ADR reporting is not surprising, as most pharmacists universally feel responsible for medicine safety. This belief of being responsible for medicine safety is likely instilled early during the undergraduate studies. However, it is not always clear what prevents pharmacists from reporting ADRs even though they regard it as important. Possible explanations for this phenomenon that have been put forward include barriers pharmacists experience in the workplace which make it difficult to report ADRs and issues related to a pharmacovigilance reporting system (Elkalmi et al., 2011; Walji et al., 2011; Green et al., 2001). Pharmacists’ beliefs that ADR reporting is important, paves the way for pharmacists to play a significant role in any pharmacovigilance system, although there is a need to have a better understanding of the barriers pharmacists face in order to strengthen the pharmacovigilance system.

5.3. Pharmacists identify ADR reporting opportunities and enable other HCPs to report ADRs

The study revealed that pharmacists identify ADR reporting opportunities during their normal clinical work and enable other HCPs to confirm the occurrence of an ADR and report it. Pharmacists primarily identify ADRs when they scan patient folders for any clues that could indicate that an ADR had occurred. A pharmacist might only identify an ADR after a considerable time period while going through a patient’s folder which would lead to delayed reporting. An ADR reporting opportunity may be identified in various ways. Firstly, when the
pharmacist observes that the patient’s medication was changed, possibly in response to an ADR experienced by the patient. Secondly, when the pharmacist observes in the patient’s file that the medical officer identified an ADR and recorded the details in the patient’s file without reporting the ADR. Thirdly, when the patient discloses to the pharmacist during the counselling session that he/she has possibly experienced an ADR.

Some pharmacy staff directly report an ADR based on the information available in the patient’s folder. In most cases however, the patient is referred back to the medical officer to complete the ADR reporting template. Pharmacists therefore help prevent the under reporting of ADRs by identifying missed ADR reporting opportunities and enabling other HCPs to report. Inappropriate ADR referrals, i.e. referrals that not linked to a possible ADR occurrence, could however add to the workload of medical officers.

Not much has been reported in previous literature on the pharmacist’s role in identifying ADR reporting opportunities, although some research has pointed to the use of medical records as a source of identifying missed ADR reporting opportunities (Khan et al, 2015; Henriksson et al., 2015). These researchers explored utilizing detailed electronic medical records to identify potential ADRs, either from electronic clinical notes made by medical officers or scrutinizing certain medications prescribed as antidotes to counter the effects of ADRs caused by other medication (Khan et al., 2015; Henriksson et al., 2015). Once implemented, such systems could be highly accurate in identifying missed ADRs with minimum costs compared to traditional methods (Khan et al., 2015). The research confirms that clinical records and notes in patient files can indeed be used to identify missed ADR reporting opportunities. The difference shown by the research mentioned, compared with the finding in this study is that pharmacists manually evaluate medical records for signs of ADRs that could have occurred. The ability to identify ADR reporting opportunities from medical notes is thus based on the clinical expertise and experience of the pharmacists in the study. In the absence of an automatic identification system utilizing electronic patient records, pharmacists with the appropriate training could therefore assist in identifying ADR reporting opportunities and help reduce the under-reporting of ADRs.

This finding tells us that pharmacists in the study were sensitized to ADR reporting and could
play an important role in preventing missed ADR reporting opportunities. This study provides
detailed information on this point, which would be of value in future training sessions and could
strengthen pharmacovigilance practices at primary healthcare level. Future training should thus
concentrate on improving the quality of referrals back to medical officers and enabling
pharmacists to have more confidence reporting ADRs directly from information available in
patients’ files.

5.4. Pharmacists associate an ADR with a therapeutic intervention

Alongside the previous finding, some pharmacists in the study associated an ADR with a
therapeutic or clinical intervention. In general, therapeutic interventions usually involved a
clinical action more closely associated with medical officers and were viewed by pharmacists in
the study as being outside their legal and clinical scope of practice. A clinical intervention could
include a change of medication, change of dose, and other prescription changes or might involve
the medical officer referring the patient to a higher level of care depending on the severity of the
suspected ADR. A clinical intervention could include performing complex diagnostic tests,
observations and laboratory investigations.

A change in prescription of medication could be an action needed to reduce or prevent the
suspected ADR. Performing diagnostic tests might be needed to help determine the cause of the
ADR. A pharmacist is not allowed to conduct the above mentioned examples of clinical
interventions as they fall outside their legal and clinical scope of practice in South Africa
(Pharmcouncil.co.za, 2015). This finding compares well with Walji’s et al. (2011) study in which
pharmacists also referred patients to medical officers even though they themselves identified the
ADR. They had a similar view that the medical officers had a better clinical picture of the
patient’s health status, including access to diagnostic tests, as well as better access to all the
information required to complete the ADR report form (Walji et al., 2011). Mahmoud (2014)
also reported that community pharmacists would advise patients presenting with an ADR at the
pharmacy to consult a general practitioner for further management. Although pharmacists in
the study had similar views, the difference compared with Walji et al. (2011) was that pharmacists in
this study believed that a therapeutic intervention needed to take place as a consequence of an
identified ADR. Patients could experience an underlying disease that could add to the complexity of determining the cause of the ADR. Pharmacists could be afraid of submitting inappropriate reports that could be linked to insecurities in performing actions outside their scope of practice (Green et al., 2001). Pharmacists might be fearful of accepting professional liability and thus run the risk of being disciplined by superiors or fear of looking ludicrous in reporting ADRs (Visacri et al, 2015; Aljadhey et al., 2014). Pharmacists association of an ADR experience with a clinical intervention is an important factor limiting their reporting of ADRs.

The result of this belief of pharmacists is that patients are referred from the pharmacy back to medical officers for the clinical intervention. In this way, although pharmacists do not directly report an ADR, their referral to medical officers would help improve reporting of ADRs. This finding is consistent with the first finding as it offers an explanation why pharmacists, while they acknowledge the importance of ADR reporting, do not themselves necessarily report. Furthermore, although pharmacists identify ADR reporting opportunities during their routine work, they might not necessarily submit reports it as they associate an ADR with a possible therapeutic intervention that needs to take place in the interest of the patient.

Although pharmacists in the study acknowledge their role as the drivers and gatekeepers of the reporting process, they acknowledged the responsibility of other HCPs to report ADRs. Walji et al. (2011) reported that pharmacists’ overlapping responsibility with other HCPs in terms of pharmacovigilance outcomes could contribute to under-reporting of ADRs, as shared responsibility may mean that no one takes responsibility to report. In this research, however, pharmacists appeared to complement medical officers by referring suspected ADRs for their management. It is thus important in any pharmacovigilance system to identify shared responsibility amongst HCPs but at the same time acknowledge the roles, skill sets and abilities of different HCPs to enable them to complement each other in strengthening the reporting process. It is evident from the study that a complex relationship exists between pharmacists and other members of the multidisciplinary team, particularly with medical officers and nursing staff. This relationship has implications for patient management as seen in the patient referrals from pharmacists to medical officers.
Although pharmacists in the study strongly identified being gatekeepers and drivers of the reporting process, they should not be limited to this role in ensuring medication safety as part of the multidisciplinary team. It is important to note that most ADRs are preventable and reversible through early identification, improving medicine use, reducing prescriber errors and prompt management of the ADR (Jose et al., 2014, Shamna et al., 2014; Khan et al., 2013; Mehta, 2011). Pharmacists can play a great role in improving medication safety as part of the multidisciplinary team by enforcing principles of Rational Medicine Use and through identification and feedback of prescribing errors. Pharmacists are also in an ideal position to affect patient behaviors through adherence counseling. Patients might exhibit behavior which could add to the risk of an ADR from the use of over-the-counter medications, the use of natural health products, smoking and increased alcohol intake (Alomar, 2014; Shaw et al., 2012). Smoking and alcohol intake could have an effect on the metabolism of medication. Over-the-counter medication could interact with prescribed medication leading to increased risk of an ADR (Alomar, 2014). Certain categories of patients, such as the elderly, are more at risk of ADRs due to altered metabolism of medication and the potential of poly-pharmacy in such patients which requires a greater vigilance on the part of pharmacists (Alomar, 2014). Pharmacist counseling of patients could help prevent ADRs through the correct use of medication by patients (Jose et al., 2014; Mehta, 2011).

5.5. Pharmacists feel that common ADRs should be reported

An unexpected and contrasting finding compared to previous research was the strong belief of some pharmacists in this study that common ADRs should be reported. Pharmacists believed that by reporting common ADRs en masse, authorities might decide to remove the problematic medication from the approved public sector formulary. This is in contrast to previous research where pharmacists either acknowledge that authorities only want novel or serious ADRs from newly marketed medication and believe that reporting well-known ADRs is a waste of time (Green et al., 2001). Green et al. (2001) reported that pharmacists in their study had the view that reporting minor ADRs would not really contribute to improved medicine safety. Although certain changes were made in the past to ARV guidelines after reports of serious ADRs, it is not clear if a problematic medication has been removed from the approved formulary because of the volume of ADR reports received. There is, however, local evidence that medication has been
added to the formulary as an option to counter the effects of a common ADR associated with a routinely prescribed medication. One of the most common ADRs to be reported is cough associated with the use of a hypertension medication called enalapril, which is classified as an essential medication. After numerous ADR reports losartan was added by the Provincial Pharmacy and Therapeutics Committee (PPTC) to the approved formulary as an option for patients suffering from cough associated with enalapril. (See Appendix 9, page 102)

The belief that an emphasis should be placed on the reporting of common ADRs is in contrast with previous research, which showed that pharmacists were reluctant to report clinically insignificant and well-known ADRs and were more motivated to report rare and serious ADRs (Elkalmi et al., 2011). A provincial pharmacovigilance circular issued by the Western Cape Department of Health in 2013 advises HCPs to report serious, rare and novel ADRs only (see Appendix 5, page 86). Whilst pharmacists might find it easier to report common ADRs that are easy to identify and that probably do not require much clinical intervention, the question is: should valuable time be ‘wasted’ on the reporting of ADRs that are common and well reported in the past? The exception should be reporting common quality issues associated with new generic medication as inferior quality medication could have a significant impact on a patient’s therapeutic outcomes. It has been suggested that in a resource-constrained environment greater emphasis should be placed on reporting ADRs associated with novel medication and rational medicine use interventions that could help prevent ADRs and other complications (Alomar, 2014)

5.6. Barriers to reporting ADRs

Pharmacists reported that they faced several barriers in reporting ADRs. The main barriers mentioned were a lack of adequate feedback, heavy workload and time constraints, uncertainty in identifying the cause of an ADR and issues pharmacists had with the reporting process. These barriers have been mentioned by several researchers prior to this study (Elkalmi et al., 2011; Walji et al., 2011; Green et al., 2001).

Heavy workload and time constraints are repeatedly mentioned in published literature as reasons
for under-reporting of ADRs. Heavy workload leads to other tasks being prioritized above pharmacovigilance activities, leading to under reporting. Completing another form is seen as adding to the already over-laden paperwork burden experienced by HCPs. Pharmacists had conflicting views on how quick it was to report an ADR and whether workload could be offered as an excuse to not report an ADR. A possible reason for this could be the difference in reporting common, easy ADRs, compared with ADRs that are more complicated. Completing a common, well-known ADR could be a relatively quick and easy task for most pharmacists. Time constraints and workload, however, remains a valid concern. To lessen the impact of this universal obstacle, managers should ensure that adequate continuous training and awareness are provided to all HCPs (Elkalmi et al., 2011).

A lack of adequate feedback was the most common barrier to reporting ADRs mentioned by pharmacists in this study. Previous research has confirmed that appropriate feedback is essential in facilitating ADR reporting (Elkalmi et al., 2011). There was no common response as to what type of feedback pharmacists preferred. Interestingly the “Dear Doctor” letter or medicine warning document sent to all HCPs were not really regarded as a type of feedback by pharmacists in this study. Due to lack of resources, the National Pharmacovigilance Centre (NPC) would not be able to provide individualized feedback for every ADR report (Dheda, 2013). In the Western Cape Province, a quarterly provincial pharmacovigilance report detailing number of reports submitted, medication involved and type of ADRs reported is currently being provided by the Medicine Information Centre in conjunction with the Department of Health’s PPTC to all HCPs.

Providing continuous feedback helps with creating awareness but does it aid in improving the management of ADR cases in especially primary healthcare settings? Dheda (2013) reported on the initial success of a decentralized pharmacovigilance system which consisted of multidisciplinary cluster-based teams. These teams received training on pharmacovigilance activities and relied on expertise within the team to help improve the management of ADR cases on the ground through monthly meetings (Dheda, 2013). The NPC would then provide guidance on trends observed from reports received by the multidisciplinary cluster-based teams. In future, as part of a multidisciplinary team, pharmacists would be called upon to provide statistical
feedback to team members as opposed to receiving individualized feedback from the NPC.

Uncertainty in identifying the possible cause of an ADR and an accompanying lack of identification skills were reported by pharmacists in the study as a reason for under-reporting. Previous research confirmed this as a barrier contributing to under-reporting (Jose et al., 2014; Ruud et al., 2010; Suleman, 2010; Green et al., 2001). Furthermore, one pharmacist interestingly noted that the long list of chronic medications (sometimes in excess of seven items) that patients are on seems to complicate the process of identifying which medication is potentially responsible for the suspected ADR. Poly-pharmacy, where a patient is on a long list of medications, is widely recognized as a contributing factor in increasing the risk of an ADR (Alomar, 2014; Khan et al., 2013). Obviously, the more medication the patient is on, the greater the risk of an ADR experienced due to an increase risk of medication interactions (Alomar, 2014). Poly-pharmacy can also lead to prescribing cascades, meaning that other medications are prescribed to help reduce the adverse effects of medication already prescribed (Alomar, 2014). Pharmacists are not really in the position to ascertain which of the prescribed medication could be responsible for the suspected ADR due to a lack of available time, experience and reference resources. Nevertheless, pharmacists could play an important role in helping to prevent ADRs by promoting the principles of Rational Medicine Use, reducing prescriber made errors and improving adherence on chronic medication. Rational Medicines Use requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (WHO, 2016).

The impact of this barrier could be mitigated by the use of an ADR causality assessment tool. ADR identification decision aids, such as the Naranjo, Yale and Karch algorithms have been developed in the past (Doherty, 2009). Although the Naranjo algorithm is commonly used, no universal “Gold Standard” causality assessment tools have yet been developed (Doherty, 2009). A causality assessment algorithm which could identify the link between an ADR and a suspected medication, when applied to information available in electronic medical records, would be beneficial (Khan et al., 2015; Maitra et al., 2014). In our situation however, where electronic medical records have not been universally implemented, pharmacists could find benefit in a manual causality assessment tool that aims to remove some of the uncertainty in identifying the
possible cause of an ADR.

Pharmacists had conflicting viewpoints on the user friendliness of the ADR reporting form. Some pharmacists mentioned that there were three different reporting forms – one for ART and TB medications, one for vaccines and one for other medicines. The study highlighted recent efforts made by the MIC to simplify the reporting template. This involved combining two previous forms used to report different medication and to decrease writing by adding tick boxes. A complicated reporting template could be viewed as a barrier to under-reporting.

The user-friendliness of the reporting template should be taken into account with different types of ADRs that are reported. It is understandable that pharmacists may find it easier to complete the reporting template for common, well-known ADRs, requiring little supporting information than difficult unknown ADRs.

Some pharmacists reported the part of the reporting form requiring information about sequelae as being problematic, as they would not have access to that information especially if the patient has been referred to another institution. Therefore, a reporting template requiring information pharmacists do not have ready access to might be viewed as difficult. It is important to note that reporting templates should be as user-friendly as possible for all HCPs. Not having access to all the required information should not deter pharmacists and other HCPs from reporting ADRs. However, members of the multidisciplinary team should be supported by each other to complete the reporting form as accurately as possible.

In this study, pharmacists reported that the availability of the reporting form was not reported as being a barrier and they indicated that it was relatively easy for HCPs to obtain copies of the reporting from the pharmacy. Pharmacy staff could either fax blank forms or send forms electronically which could then be printed by HCPs. As pharmacy staff were primarily responsible for the distribution of the reporting form copies, it would be unlikely that pharmacists would raise the availability of the reporting form as a barrier or reason for under reporting. A future recommendation would be to make the availability of ADR forms part of the verification pharmaceutical audit conducted by pharmacy staff. The pharmaceutical verification audit is an inspection based on South African Pharmacy Council guidelines and aims to improve
pharmaceutical norms and standards (See Appendix 10, page 109). In the Western Cape, this audit is only conducted in the Cape Winelands and in a similar format in the Overberg District. When facilities are audited, clinic managers should be asked to display ADR reporting forms in the various consultation rooms.

Pharmacists in the study had a varied understanding of the pharmacovigilance system. There was a marked difference in terms of knowledge about how the pharmacovigilance system works between supervisor pharmacists and production pharmacists. This could be attributed to supervisor pharmacists being more involved in attending meetings and having better access to communication, such as circulars, compared to production pharmacists. Supervisor pharmacists have more management tasks compared with production pharmacists and probably have a higher sense of being responsible as gatekeepers of the reporting process. Another research study has also reported on differences observed between different categories of pharmacists. Suyagh et al. (2015) reported on the difference in knowledge and awareness of the pharmacovigilance system observed between hospital and community pharmacists. Suyagh et al. (2015) speculated that the possible reason for this could be due to hospital pharmacists being more in contact with other HCPs and thus more exposed to scenarios where they have to give advice or support in the identification process of ADRs. In contrast to Suyagh’s et al. (2015) research study, all pharmacists in this study were part of an integrated district healthcare system with daily contact between district hospital and clinic-based pharmacists and other HCPs. In general there did not appear to be any difference between supervisor pharmacists based at district hospitals and those at clinics in terms of knowledge and awareness of the pharmacovigilance system. Nevertheless, lack of knowledge about the pharmacovigilance system was not raised in this study as a barrier, which is in contrast with other research conducted. In the Suyagh et al. (2015) and Elkalmi et al. (2011) studies, poor knowledge amongst pharmacists about their pharmacovigilance system was found to be a great contributing factor for under-reporting of ADRs by pharmacists.

5.7. Facilitation of ADR reporting

Pharmacists suggested various means of facilitating ADR reporting including electronic reporting aids, creating increased awareness amongst healthcare professionals, conducting
continuous training and making amendments to the reporting form, which were in line with previous research conducted (Elkalmi et al., 2011; Walji et al., 2011; Green et al., 2001). Some pharmacists in the study mentioned providing continuous training sessions as a means to improve ADR reporting. This notion is well supported by previous research conducted (Elkalmi et al., 2011; Green et al., 2001). Green et al. (2001) reported that pharmacists who received training were more likely to report ADRs and had a better understanding of the pharmacovigilance system. Other research reported on a separate incentive to report ADRs as a means to facilitate reporting, either in favor or against it. This not only included financial incentives but other incentives such as receiving recognition or journal subscriptions (Elkalmi et al., 2011).

Interestingly, receiving a financial incentive was not reported as a means to facilitate ADR reporting by pharmacists in this study. This could be due to pharmacists’ high sense of responsibility being the drivers and gatekeepers of the reporting process. It is important to note that providing a financial incentive could be a double-edged sword in facilitating ADR reporting in that a substantial incentive could increase minor ADR reporting with little benefit to medication safety, whereas if the incentive was small pharmacists might consider it not a worthwhile action (Elkalmi et al., 2011; Green et al., 2001).

One recommendation mentioned by a pharmacist and key stakeholder was to make pharmacovigilance part of the performance management of pharmacy staff in the province. In this way performance management could provide an incentive to pharmacists who exceeded expectations in improving pharmacovigilance outcomes which would be beneficial in keeping all pharmacy staff accountable for improving ADR reporting.

Creating continuous awareness is essential for ensuring that HCPs do not under report ADRs. The study highlighted various means of creating awareness of the reporting process, such as using the PTC, clinical morbidity and mortality meetings and other meetings with the medical officers where pharmacists could give feedback and provide additional information. Creating awareness as a means to increase ADR reports is in line with previous research (Green et al., 2001). These recommendations mentioned by pharmacists in the study are significant in moving
towards a decentralized pharmacovigilance system as reported by Dheda (Dheda, 2013).

The study found that respondents felt that the use of technology could help in enabling quicker and more accurate reporting of ADRs and provide a means to give specific feedback through electronic means. Whilst the use of electronic reporting could offer advantages for more efficient reporting, it was mentioned that the technological infrastructure should first be created to facilitate electronic reporting. Previous research has mentioned electronic reporting as a means to help improve pharmacovigilance outcomes (Elkalmi et al., 2011). It should be noted that Kenya has already implemented an electronic ADR reporting system that greatly improved the rate of reporting in that country (Otieno, 2013). The decentralized pharmacovigilance system in Mpumalanga Province could perhaps be a good setting to pilot a similar electronic system as seen in Kenya.
CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1. Conclusion

The findings of this study contribute to our understanding of the role of rural pharmacists in the public healthcare system in South Africa in supporting a spontaneous reporting pharmacovigilance system. Pharmacists’ positive acknowledgement of the importance of ADR reporting is significant in improving the pharmacovigilance system as they are willing to cooperate in improving it, especially in moving towards a decentralized pharmacovigilance system as proposed by Dheda (2013).

Although pharmacists did not directly report ADRs they contributed to improve pharmacovigilance outcomes through identification of ADR reporting opportunities and reducing under-reporting by enabling and supporting other HCPs to report. Although this gatekeeper and supportive role pharmacists play is important, more work needs to be done to create awareness amongst pharmacists that improving medicine use outcomes and reducing prescribing errors will help prevent ADRs.

The study highlighted two beliefs held by pharmacists which have implications for future efforts to improve or change the pharmacovigilance reporting system. Firstly, pharmacists’ belief that common ADRs should be reported was a contrasting finding to other research on this topic. Secondly, pharmacists’ association of ADRs with a therapeutic intervention was a novel finding compared with other research. This finding illustrates the complex relationship that exists between pharmacists and medical officers.

The study illustrates reasons for under-reporting and barriers faced by pharmacists in reporting ADRs. Future pharmacovigilance training for pharmacists is essential in reducing the negative impact of these barriers by improving pharmacovigilance knowledge and understanding amongst pharmacists. This would enable them to make better operational and clinical decisions, for example, improving pharmacists’ understanding of which medicine might be responsible for an ADR could lead to less time being wasted trying to identify which medication is responsible,
improving reporting rates and reducing inappropriate referrals to medical officers. In addition, pharmacists could play key roles as gatekeepers and drivers of pharmacovigilance reporting systems, enabling other HCPs to report ADRs by identifying ADR reporting opportunities, creating continuous reporting awareness and providing appropriate feedback as part of a future multidisciplinary decentralized pharmacovigilance team.

### 6.2. Recommendations

Several key recommendations are proposed:

1. Future circulars, training workshops and awareness posters about the ADR reporting process should inform all HCPs to report any medication suspected of being the cause of an ADR and not waste time in trying to identify the medication that caused it. The message should be: If you suspect an ADR, report it.

2. Training workshops should be conducted with pharmacists to improve their skills in terms of identifying ADRs, how and what to report and the appropriate referral of patients to the medical officers. The training should also emphasize the link between improving rational medicine use outcomes, reducing prescribing errors and preventing the occurrence of ADRs.

3. An annual assessment on the availability of reporting forms in all health facilities should be conducted. This assessment should include pharmacies and clinical consultation rooms. In addition, the MIC should conduct a survey on the user-friendliness of the reporting form and enable HCPs to provide recommendations to help improve the reporting form template.

4. Pharmacovigilance should be a standing item on the agendas of sub-district PTC meetings at which supervisor pharmacists should give quarterly updates to sub-district management on ADRs reported. Promoting pharmacovigilance should be part of pharmacy staff job descriptions and performance agreements. Newly appointed HCPs
coming into the healthcare system, such as community service pharmacists, nurses and medical officers should be orientated and informed about the pharmacovigilance system in place.

5. As this study focused primarily on the experiences and perceptions of pharmacists in the rural health district, a follow-up study should explore perceptions and knowledge of medical officers and nurses of ADR reporting, specifically on the availability and complexity of the reporting form.

6. The MIC should explore the development of a basic ADR causality assessment tool that could assist pharmacists and other HCPs in identifying a possible ADR and improve confidence amongst pharmacists and HCPs in reporting ADRs. Such a tool would also aid in raising pharmacovigilance awareness amongst pharmacists and HCPs but would need to be linked with appropriate training before such a tool could be implemented.
REFERENCES


Appendix 1: Consent Form

UNIVERSITY OF THE WESTERN CAPE

School of Public Health
Private Bag X 17, Bellville 7535, South Africa
Tel: +27 21-9592809, Fax: +27 21-9592872
http://www.soph.uwc.ac.za

CONSENT FORM

Title of Research Project: Reasons for under-reporting of Adverse Drug Reactions by pharmacists in the public sector in a rural district in the Western Cape Province, South Africa.

The study has been described to me in language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered.

I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant’s name:

Participant’s signature:

Witness:

Date:

Student no: Charles Williams (9900806)
Cell phone: 076 540 6656
Telephone at work: 023 348 8115

I am accountable to:
Hazel Bradley BPharm, MPH
School of Public Health, University of the Western Cape, SOUTH AFRICA
Tel: +27 21 959 2630
Fax: +27 21 959 2872
E-mail: hbradley@uwc.ac.za
Head of School of Public Health: Prof Uta Lehmann
Tel: +27 21 959 2809
E-mail: ulehmann@uwc.ac.za
Appendix 2: Cape Winelands District Population Figures

<table>
<thead>
<tr>
<th>Population Used for Indicators</th>
<th>Breedekloof</th>
<th>Drakenstein</th>
<th>Stellenbosch</th>
<th>Swellendam</th>
<th>Villiersdorp</th>
<th>Cape Winelands District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total population</td>
<td>179,481</td>
<td>249,725</td>
<td>160,025</td>
<td>165,583</td>
<td>128,042</td>
<td>640,237</td>
</tr>
<tr>
<td>Unmarried Pop. 10-19 at total population</td>
<td>129,962</td>
<td>190,658</td>
<td>74,596</td>
<td>117,663</td>
<td>48,617</td>
<td>596,005</td>
</tr>
<tr>
<td>Male Pop. 15-49 years &amp; older</td>
<td>61,430</td>
<td>96,815</td>
<td>35,932</td>
<td>47,461</td>
<td>47,483</td>
<td>303,319</td>
</tr>
<tr>
<td>Female Pop. 15-49 years &amp; older</td>
<td>68,519</td>
<td>77,416</td>
<td>38,655</td>
<td>69,202</td>
<td>28,724</td>
<td>246,627</td>
</tr>
<tr>
<td>Female Pop. 30 years &amp; older</td>
<td>46,125</td>
<td>48,599</td>
<td>26,004</td>
<td>24,179</td>
<td>26,569</td>
<td>206,956</td>
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<tr>
<td>Pop. 60 years &amp; older</td>
<td>52,677</td>
<td>64,672</td>
<td>22,791</td>
<td>26,632</td>
<td>32,569</td>
<td>163,212</td>
</tr>
<tr>
<td>Pop. 15-49 years</td>
<td>99,486</td>
<td>154,577</td>
<td>54,864</td>
<td>101,942</td>
<td>75,564</td>
<td>487,799</td>
</tr>
<tr>
<td>Children &lt;1 year</td>
<td>3,364</td>
<td>4,037</td>
<td>1,951</td>
<td>2,655</td>
<td>2,075</td>
<td>14,908</td>
</tr>
<tr>
<td>Children 1-4 years</td>
<td>3,279</td>
<td>4,048</td>
<td>1,942</td>
<td>2,724</td>
<td>2,079</td>
<td>14,977</td>
</tr>
<tr>
<td>Children 5-19 years</td>
<td>13,542</td>
<td>19,299</td>
<td>7,956</td>
<td>10,936</td>
<td>8,365</td>
<td>69,992</td>
</tr>
<tr>
<td>Children &lt;5 years</td>
<td>16,906</td>
<td>24,696</td>
<td>9,797</td>
<td>13,589</td>
<td>10,421</td>
<td>74,900</td>
</tr>
<tr>
<td>Children 0-4 years</td>
<td>50,101</td>
<td>69,329</td>
<td>29,992</td>
<td>38,338</td>
<td>31,817</td>
<td>219,537</td>
</tr>
</tbody>
</table>
Appendix 3: Department of Health ARV ADR reporting form

<table>
<thead>
<tr>
<th>Western Cape ARV Suspected Serious Adverse Drug Reaction Reporting Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Initials:</td>
</tr>
<tr>
<td>Weight (in kg):</td>
</tr>
<tr>
<td>Treatment facility name:</td>
</tr>
<tr>
<td>Referral Hospital name:</td>
</tr>
<tr>
<td>Female patients only:</td>
</tr>
<tr>
<td>Medication history (circle suspected medicines and provide brand names where available):</td>
</tr>
<tr>
<td>Antiretroviral Medicines</td>
</tr>
<tr>
<td>ARV</td>
</tr>
<tr>
<td>Date ART was first commenced in this patient:</td>
</tr>
</tbody>
</table>

**Adverse Event Details (Indicate with an “X” all that apply):**

(see back for case definitions of adverse events)

- Death: Suspected Cause of Death:  
  - Symptomatic hyperlactataemia  
  - Lactic acidosis  
  - Grade 3 or 4 transaminitis/Symptomatic hepatitis  
  - Serious skin reaction  
  - Pancreatitis  
  - Neutropenia with Neutrophil count < 0.5 *10^9 cells/mm³  
  - Anaemia requiring transfusion  
  - Congenital anomaly/Pregnancy exposure  
  - Any other serious or unusual event: Specify and Describe: Describe:  

Provide event details (including relevant signs and symptoms): Date event started:  

Investigations (including other relevant medical history):  

Management of adverse event:  

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Died</th>
<th>Recovered</th>
<th>No yet recovered</th>
<th>Permanent damage/disability</th>
<th>Hospitalised</th>
<th>Regimen change - speech:</th>
</tr>
</thead>
</table>

Response to rechallenge (if applicable):  

Other outcome - specify:  

Completed by: Job title:  

Signature: Date completed:  

Please include additional information that you may deem necessary in your report (use additional paper)

This report can be submitted either immediately on with monthly reports by Fax (021) 481 6003 or emailed to pgwchirnb@gmail.com
ARV Clinic Serious Adverse Event Reporting Form

Guidelines for Reporting

Report even if:
- You're not certain the product caused the event
- You don't have all the details

Whom to report to:
All reports should be submitted by fax: (021) 483 6033 OR emailed to pgwhivtb@gmail.com

When to report:
All forms should be completed immediately and submitted with routine monthly reports

Further Information:
For further information or help with reporting contact the HIV/AIDS Hotline Tel: (021) 406 6782
Please use additional paper to include any other relevant information you deem necessary.

Important Definitions for Reportable Events

Serious Adverse Event:
Any adverse event that a) results in death; b) is life-threatening; c) requires patient hospitalisation or prolongation of existing hospitalisation, d) results in persistent disability or incapacity, e) is a congenital anomaly or birth defect. Medical judgement should be used when deciding if other situations are serious. For the purposes of the ART programme an adverse event warranting a regimen change is also considered serious.

Symptomatic Hyperlactataemia:
Lactate >2 mmol/l in combination with one or more of the following symptoms: fatigue, myalgia, nausea, vomiting, diarrhoea, abdominal distension, abdominal pain, weight loss and shortness of breath

Lactic Acidosis:
Metabolic acidosis with elevated lactate (>2 mmol/l)

Grade 3 or 4 Transaminis / Symptomatic Hepatitis:
Grade 3 transaminis: ALT 5-10 times the ULN, Grade 4 transaminis: ALT >10 times ULN

Severe Skin Reaction:
 rash with involvement of mucosal surfaces OR systemic features including fever OR any derangement of liver or renal function.

Grade 4 Neutropenia:
Neutrophil count less than 0.5 x 10^9/Litre

This report does not constitute an admission that medical personnel or the product caused or contributed to the event. Your anonymised report will be communicated to the National Adverse Drug Event Monitoring Centre and the national HIV/AIDS pharmacovigilance units

Thank you for Reporting!
Appendix 4: Provincial Pharmacovigilance Circular 2008

CIRCULAR H69/2008

TO: ALL CHIEF DIRECTORS, REGIONAL HEADS, DIRECTORS, HEADS OF INSTITUTIONS

FOR ATTENTION: ALL MEDICAL, PARAMEDICAL, PHARMACY AND NURSING PERSONNEL

REPORTING OF ADVERSE DRUG REACTIONS, OTHER THAN VACCINES


It is required that all health professionals report on adverse drug reactions as set out in this circular.

The aim of adverse drug reaction reporting is to improve the safe and rational use of medicines.

An adverse drug reaction (ADR) involves any reaction to a medicine which is noxious or unintended, and which occurs at doses normally used for the prevention, treatment or diagnosis of disease.
A well-completed adverse drug event form submitted could result in:

1. Investigations into the use of the medication in South Africa.
2. Educational initiatives to improve the safe use of the medicine.
3. Appropriate package insert changes to include the potential for the reaction reported.
4. Changes in the scheduling or manufacture of the medicine to make the medicine safer for use.

Annexure A contains the guidelines for reporting of adverse drug reactions to medicines other than vaccines.

Annexure B is the Adverse Drug Event and Product Quality Problem Report Form (form GW 12/45).

You are requested to ensure that this reporting procedure is implemented in your institution.

FINITE K LOWENHEIM
DIRECTOR: PROFESSIONAL SUPPORT SERVICES
DATE: 26/06/2008

CIRCULAR 69/2008: GUIDELINES FOR REPORTING ON ADVERSE DRUG MEDICINE REACTIONS
DATE: 13 JUNE 2008
GUIDELINES FOR REPORTING ON ADVERSE DRUG / MEDICINE REACTIONS OTHER THAN VACCINES

INTRODUCTION

The aim of adverse drug reaction reporting is to improve the safe and rational use of medicines.

An adverse drug reaction (ADR) involves any reaction to a medicine which is noxious or unintended, and which occurs at doses normally used for the prevention, treatment or diagnosis of disease.

The National Adverse Drug Event Monitoring Centre (NADEMC), a unit within the Medicine Control Council, is responsible for collecting, assessing and communicating information on adverse drug reactions in South Africa.

The Provincial Pharmacy and Therapeutics Committee monitors adverse drug reactions within public sector health facilities in the Western Cape.

An adverse drug reaction that is vaccine related must be reported following the procedure with regards to Adverse Events Following Immunisation (AEFI) according to the Expanded Programme on Immunisation (EPI).

Product / medicine quality concerns: Although the form is called Adverse Drug Event and Product Quality Problem Report Form (GW 12/45), do not report product quality problems on this form.

Product quality concerns must be reported on the PGWC Medicine Complaint Form according to the Pharmacy Services Standard Operating Procedure 5.18 (SOP 5.18) issued 09 May 2003 which describes the management of reporting of product quality problems.
WHO SHOULD REPORT?

1. All healthcare professionals, including doctors, dentists, pharmacists and nurses are requested to report.

2. Ideally, reports should be completed or checked by the patient's doctor in order to obtain all relevant information.

WHAT SHOULD BE REPORTED?

1. Report the following Adverse Drug Reactions:

   ➢ All adverse drug reactions to newly marketed medicines.

   ➢ All serious reactions and interactions (i.e. reactions resulting in death, disability, hospitalisation, or requiring intervention to prevent permanent impairment).

   ➢ Adverse drug reactions which are not clearly stated in the package insert.

   ➢ Unusual or interesting adverse drug reactions.

   ➢ Adverse reactions or poisonings to traditional or herbal remedies.

Please note:
It is vital to report an adverse drug reaction to the NADEMC even if:

➢ You do not have all the facts / details or
➢ You are uncertain that the drug is definitely responsible for causing the reaction
HOW TO REPORT A SUSPECTED ADVERSE DRUG REACTION

1. If an adverse drug reaction is vaccine related, follow the reporting procedure with regards to AEFI according to the EPI programme.

2. If the suspected adverse reaction is due to a medicine (medical device or biological) other than a vaccine, proceed as follows:

   2.1 It is important to inform the patient that the reaction will be reported to the NADEMC in the interest of public safety.

   2.2 Fill in the Adverse Drug Event and Product Quality Problem Report form (GW 12/45) in as much detail as possible.

   2.3 If you need to provide more information than can be accommodated on the form (e.g. laboratory results, etc.), please attach a separate sheet of paper.

   2.4 Ensure that correct dates and times of administration for all medicines being used by the patient at the time are recorded.

   2.5 Clearly mark the cover of the patient folder with a warning of an Adverse Drug Reaction.

   2.6 Consider the following points when completing the form:

   - What is the nature of the reaction? (Describe the reaction as clearly as possible.)
   - When did the reaction occur in relation to the starting or stopping of treatment with the suspected medicine?
   - Is the reaction stated in the package insert of the medicine?
   - Did the patient recover when the medicine was stopped?
   - Did the patient take the medicine again after the reaction occurred (i.e. rechallenged)? If so, did the same reaction occur again?
   - Can this reaction be explained by other causes (e.g. patient's disease; over-the-counter medicines; traditional medicines; toxins or foods)?
2.7 A copy of the completed form must be submitted to your Regional Pharmacist for tabling at the Regional Pharmacy and Therapeutics Committee.

2.8 Fold the original form in thirds and mail it to the Registrar of Medicines at the Medicines Control Council (MCC). The address of the Registrar of Medicines of the MCC is printed on the outside of the form (GW 12/45) and postage is prepaid.

2.9 If copies of forms are used, it must be posted to:

<table>
<thead>
<tr>
<th>Registrar of Medicines</th>
<th>OR</th>
<th>NADEMC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines Control Council</td>
<td>c/o Dept. of Pharmacology</td>
<td>University of Cape Town</td>
</tr>
<tr>
<td>Department of Health</td>
<td>Observatory</td>
<td></td>
</tr>
<tr>
<td>P.O. Box X828</td>
<td>7925</td>
<td></td>
</tr>
<tr>
<td>Pretoria, 0001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Identities of the reporter and patient will remain strictly confidential.

The report does not constitute an admission that the medical personnel or the product caused or contributed to the event.

Adverse Drug Event and Product Quality Problem Report Forms (form GW12/45) are available from the NADEMC:

National Adverse Drug Event Monitoring Centre
Medicines Control Council
C/O Department of Pharmacology
University of Cape Town
Observatory, 7925
Tel: (021) 447-1618
Fax: (021) 448-6181

Reference: National Adverse Drug Event Monitoring Centre (NADEMC)

Compiled by: PGWC Pharmacy Services
Dept of Health: Western Cape
Date: 13 June 2008
# ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM

**Health:**

Department:  
Health:  
REPUBLIC OF SOUTH AFRICA

---

**NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE (NADEMC)**

The Registrar of Medicines  
Private Bag X828  
PRETORIA  
0001

Fax: (021) 446-5181  
Tel: (021) 447-1618

In collaboration with WHO International Drug Monitoring Programme

---

**PATIENT INFORMATION**

Name (or initials): ..................................................  
Patient reference Number: ........................................

Sex: [ ] Male  
[ ] Female  
Age:  
DOB: / /  
Weight (kg):  
Height (cm): ..........................................................

---

**ADVERSE REACTION/PRODUCT QUALITY PROBLEM (tick appropriate box)**

- Adverse reaction  
- and/or Product Quality problem

Date of onset of reaction:  
Time of onset of reaction: hour min

Description of reaction or problem (include relevant tests/lab data, including dates):

---

### 1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)

<table>
<thead>
<tr>
<th>Trade name &amp; Batch No. (Asterisk suspected product)</th>
<th>Daily dosage</th>
<th>Route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Reasons for use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### 2. PRODUCT QUALITY PROBLEM

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Batch No.</th>
<th>Registration No.</th>
<th>Dosage form &amp; strength</th>
<th>Expiry date</th>
<th>Size/Type of container</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**PRODUCT AVAILABLE FOR EVALUATION?: [ ] Yes  
[ ] No**

---

**REPORTING HEALTHCARE PROFESSIONAL:**

**NAME** ..............................................................  
**QUALIFICATIONS** ...................................................

**ADDRESS** ............................................................

Postal code .................................. Tel: (..........) ..................................  
Signature .................................. Date

*This report does not constitute an admission that medical personnel or the product caused or contributed to the event.*

---

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ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experience with:
- medications (drugs, vaccines and biologicals)
- medical devices (including in-vitro diagnostics)
- complementary/alternative medicines (including traditional, herbal remedies, etc)

Please report especially:
- adverse drug reactions to newly marketed products
- serious reactions and interactions with all products
- adverse drug reactions which are not clearly reflected in the package insert.

Report the product quality problems such as:
- suspect contamination
- questionable stability
- defective components
- poor packaging
- therapeutic failures

Report even if:
- you're not sure the product caused the event
- you don't have all details

Important numbers:
Registered Medicines and Traditional and Herbal remedies:
- fax: (021) 448-6181
- phone: (021) 447-1518

Investigational Products and Product Quality Problems:
- fax: (012) 312-3114
- phone: (012) 312-0243

Adverse Events Following Immunisation:
- fax: (012) 312-3110
- phone: (012) 312-0032

Confidentiality: Identities of the reporter and patient will remain strictly confidential.

Your support of the Medicine Control Council's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of medicine safety and therapy in South Africa.

UNIVERSITY OF THE WESTERN CAPE

PLEASE USE ADDRESS PROVIDED BELOW- JUST FOLD IN THIRDS, TAPE AND MAIL

BUSINESS REPLY SERVICE
BESIGHEIDSANTWOORDDIENS
Free Mail Number: BNT 178

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE
PRIVATE BAG/PRIVAATSAK X828
PRETORIA
0001

No postage stamp necessary if posted in the Republic of South Africa.
Geen postzegel nodig, m.b.i. in die Republiek van Suid-Afrika.
Appendix 5: Provincial Pharmacovigilance Circular 2013

Circular H12 /2013

REPORTING, MONITORING AND RESPONSE TO ADVERSE DRUG REACTIONS [excluding VACCINES]

This circular on adverse drug reactions (ADR) replaces circular H69/2008 dated 26th June 2008.

An ADR is defined as any reaction to a medicine which is noxious or unintended, and which occurs at doses normally used for the prevention, treatment or diagnosis of disease. Reporting and monitoring of ADRs allows for opportunities to improve the safe use of medicines.

The purpose of reviewing the ADR process is to achieve integration of the current dual reporting processes:

- Targeted antiretroviral ADR’s submitted to the Medicines Information Centre (MIC)
- Spontaneous reporting of ADR’s submitted to NADeMC and regional pharmacists, according to Circular H69/2008

Integration will allow for comprehensive monitoring and standardized reporting and response to ADR’s reported in the province.
A well-completed adverse drug reaction / product quality form could result in:
1. Investigations into the use of the medication in South Africa.
2. Educational initiatives to improve the safe use of the medicine.
3. Appropriate package insert changes to include the potential for the reaction reported.
4. Changes in the scheduling or manufacture of the medicine to make the medicine safer for use.

Please find attached the following annexures to support the effective alignment of
the two current processes:
- Annexure A: Guidelines for reporting and monitoring of adverse drug reactions
  to medicines other than vaccines.
- Annexure B: Adverse Drug Reaction Reporting form [double sided: Part A: GW
  12/4S Part B: ARV / TB ADR form].
- Annexure C: ADR process flow diagram.

It is requested that the contents of this circular and annexures are implemented
accordingly at all service delivery sites; district or substructure offices; district and
hospital Pharmacy and Therapeutic Committee’s (PTC); Provincial Pharmacy and
Therapeutic Committee (PPTC); Geographic Service Area’s (GSA) and other policy
forums.

[Signature]
Prof K C Househam
HOD: Health

DATE: 18/1/2013

Amended by: Western Cape Government Pharmacy Services: May 2013
ANNEXURE A
GUIDELINES FOR REPORTING AND MONITORING OF ADVERSE DRUG REACTIONS OTHER THAN VACCINES

Introduction
An adverse drug reaction (ADR) involves any reaction to a medicine which is noxious or unintended, and which occurs at doses normally used for the prevention, treatment or diagnosis of disease.

The aim of ADR reporting is to improve the safe and rational use of medicines. This is done through the activities of two key monitoring bodies:

- The National Adverse Medicine Event Monitoring Centre (NADEMC), a unit within the Medicine Control Council (MCC), which is responsible for collecting, assessing and communicating information on adverse drug reactions in South Africa.
- The Provincial Pharmacy and Therapeutics Committee (PPTC) monitors adverse drug reactions within public sector health facilities in the Western Cape.

Who should report?
1. All healthcare professionals, including doctors, dentists, pharmacy personnel and nurses are requested to report.
2. It is however preferable that reports are checked by the prescriber in order to ensure that all relevant information is provided in order for the causality of the ADR to be established.
3. The report does not constitute an admission that the medical personnel or the product caused or contributed to the event.

What should be reported?

Report the following adverse drug reactions:

- All ADR to newly marketed medicines.
- All serious reactions [i.e. reactions resulting in death, disability, hospitalisation, or requiring intervention to prevent permanent impairment].
- All serious interactions.
- ADR that appear to be occurring more frequently.
- ADR which are not clearly stated in the package insert.
- Unusual or interesting ADR's.
- Adverse reactions or poisonings to traditional or herbal remedies.
- Therapeutic failures.

Amended by: Western Cape Government Pharmacy Services: May 2013
Please note:

It is vital to report an ADR to the NADEM even if:

- You do not have all the facts / details or
- You are uncertain that the medicine is definitely responsible for causing the reaction

How to report a suspected adverse drug reaction

1. If an adverse drug reaction is vaccine related, follow the reporting procedure with regards to ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI) according to the Expanded Programme on Immunisation (EPI) programme.

2. If the suspected adverse reaction is due to a medicine [medical device or biological] proceed as follows:

2.1 Inform the patient that the reaction will be reported to the NADEM in the interest of public safety.

2.2 Complete the ADR form in as much detail as possible to support establishment of causality:

2.2.1 ADR’s caused by antiretroviral or tuberculosis medicines: complete part B of the ADR form.

2.2.2 All other ADR’s: complete part A: GW 12/45: adverse drug reaction reporting form.

2.3 An additional sheet of paper should be submitted with the ADR form should the space be insufficient on the form.

2.4 Ensure that correct dates and times of administration for all medicines being used by the patient are recorded.

2.5 Consider the following points when completing the form:

- What is the nature of the reaction? [Describe the reaction as clearly as possible]
- When did the reaction occur in relation to the starting or stopping of treatment with the suspected medicine?
- Is the reaction stated in the package insert of the medicine?
- Did the patient recover when the medicine was stopped?
- Did the patient take the medicine again after the reaction occurred i.e. re-challenge? If so, did the same reaction occur again?
- Can this reaction be explained by other causes e.g. patient’s disease; over-the-counter medicines; traditional medicines; toxins or foods?

Amended by: Western Cape Government Pharmacy Services: May 2013
2.6 The completed ADR form should be submitted to the pharmacy or the facility manager [should the service point not have a pharmacy].

2.7 Clearly mark the cover of the patient folder with a warning of a possible Adverse Drug Reaction.

Monitoring, evaluation and response to ADR forms submitted

1. All completed ADR forms must be submitted through the service point’s pharmacy or facility manager to the Managers: Pharmaceutical Services [either hospital/district] with standard monthly reports by the 7th day of each month.

2. The responsibilities of the Managers: Pharmaceutical Services will be to ensure:
   a. accurate capture of ADR forms in the standardized database.
   b. provision of stats on the numbers of ADR reported to respective management.
   c. submission of all submitted ADR forms and database to Medicines Information Centre [MIC fax: 02144808503] by the 21st of month [following the month being reported on].
   d. submission of all ADR forms to NADEMC fax: 021 448 6181.
   e. reporting of ADRs to respective PTC for discussion.
   f. distribution of quarterly/annual reports to relevant management; PTC’s; GSA’s and pharmacy personnel.

3. The responsibilities of the MIC will be:
   a. Individual feedback to submitting health professionals.
   b. evaluation of top 10 medicines / top 10 ADR / high risk ADR’s [causality].
   c. provision of draft quarterly and annual report to PPTC for input / action decisions.

4. The responsibilities of the Provincial Pharmacy Services [PS] and Provincial Pharmacy and Therapeutics Committee [PPTC]:
   a. PPTC: Analyse draft quarterly and annual reports provided by MIC; and make recommendations for further actions, if required.
   b. PS: Finalize reports with necessary recommendations and distribute to policy advisory groups; family physicians; district and hospital PTC’s; HIA; PHC managers; Managers: Pharmaceutical Services and HAST directorate.

5. The responsibility of Provincial programmes: ensure amendment of policies if / when required on advice of the PPTC.

6. The responsibility of the services will be to ensure amended policy/guidelines are affected.

7. The Head of Pharmacy Services will feed back to National Department of Health’s respective departments: the National Essential Medicines List committee and the National Pharmacovigilance coordinator [Medicines Regulatory Authority [MRA]].

Amended by: Western Cape Government Pharmacy Services: May 2013
Product/Medicine Quality Problems: Although the form GW 12/45 is called Adverse Drug Reaction and Product Quality Problem Report, quality concerns must be completed on the Western Cape Medicine Complaint Form according to the Pharmacy Services Standard Operating Procedure 5.18 issued on 9th May 2003 which describes the management of reporting of product quality problems such as:

- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labelling
- Ineffective products
ANNEXURE B: Part A: ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM

IDENTITIES OF REPORTER AND PATIENT WILL REMAIN STRICTLY CONFIDENTIAL

NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE

PATIENT INFORMATION

Name (or initials): ____________________________ Age: ________________ Weight (kg): ________________
Sex: M F DOB: ______/______/______ Height (cm): ________________

ADVERSE REACTION/PRODUCT QUALITY PROBLEM

Adverse reaction 1 and/or Product Quality problem 2 Date of onset of reaction: ______/______/______
Time of onset of reaction: ______h ______min

Description of reaction or problem (Include relevant tests/lab data, including dates):

1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)

<table>
<thead>
<tr>
<th>Trade Name &amp; Batch No.</th>
<th>Daily Dosage</th>
<th>Route</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Reasons for use</th>
</tr>
</thead>
</table>

ADVERSE REACTION OUTCOME (Check all that apply)

<table>
<thead>
<tr>
<th>Death</th>
<th>Disability</th>
<th>Congenital anomaly</th>
<th>Required intervention to prevent permanent impairment/damage</th>
<th>Life-threatening hospitalisation</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y N</td>
<td>Y N</td>
<td>Y N</td>
<td>Y N</td>
<td>Y N</td>
</tr>
</tbody>
</table>

Event responded or rechallenged: Y N
Rechallenged not done: Y N
Treatment of reaction: __________________

Recovered: Y N
Sequelae: Y N
Describe Sequelae: __________________

COMMENTS: (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)

2. PRODUCT QUALITY PROBLEM:

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Batch No</th>
<th>Registration No</th>
<th>Dosage form &amp; strength</th>
<th>Expiry Date</th>
<th>Size/Type of container</th>
</tr>
</thead>
</table>

Product available for evaluation: Y N

REPORTING DOCTOR/PHARMACIST Etc:

NAME: ____________________________
QUALIFICATIONS: ____________________________
ADDRESS: ____________________________
Signature __________ Date __________

TEL: ____________________________

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

OFFICE USE ONLY: Database reference number: ____________________________

ANNEXURE B: Part B:

Amended by: Western Cape Government Pharmaceutical Services: May 2013
Western Cape Adverse Drug Reaction Reporting Form for patients on ARV & / or TB treatment

<table>
<thead>
<tr>
<th>Patient initials:</th>
<th>DOB:</th>
<th>Gender:</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height (cm):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant?</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
<td>N/A</td>
</tr>
<tr>
<td>Treatment facility name:</td>
<td></td>
<td></td>
<td>Folder no:</td>
<td></td>
</tr>
<tr>
<td>District/ sub-district:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICD 10 code(s) or diagnosis:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MEDICATION HISTORY (include suspected medicine)

List all medication patient was receiving at the time of the reaction including herbal, traditional and OTC medication

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Dose</th>
<th>Date started</th>
<th>Date stopped</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>Dose</td>
<td>Date started</td>
<td>Date stopped</td>
</tr>
</tbody>
</table>

ADVERSE REACTION DETAILS:

- Anemia requiring transfusion
- Cholestatic hepatitis
- Congenital anomaly/Pregnancy exposure/foetal death
- Gynaecomastia
- Hypersensitivity reaction
- Hypomagnesaemia
- Lactic acidosis (Metabolic acidosis and lactate) abnormal
- Lipodystrophy (Fat loss)
- Lipophosphatidosis (Abnormal fat accumulation)
- Neutropenia (Neutrophil less than 0.6 X 10^9)
- Other

Description of reaction: Date event started:

Investigations (including other relevant medical history):

Management of adverse event:

OUTCOME

<table>
<thead>
<tr>
<th>Died</th>
<th>Recovered</th>
<th>Not yet recovered</th>
<th>Permanent</th>
<th>Disability</th>
<th>Hospitalized</th>
<th>Regimen change</th>
<th>Specify:</th>
</tr>
</thead>
</table>

Other outcome - specify:

REPORTING DOCTOR / PHARMACIST / PROFESSIONAL NURSE

Name: Qualifications:
Email: Tel: Cell:
Signature: Date completed:

Please include additional information that you may deem necessary in your report (use additional paper)

OFFICE USE ONLY: Database reference no: Submit to Manager: Pharmaceutical Services

Amended by: Western Cape Government Pharmaceutical Services: May 2013
### Responsibility of: Clinicians / Nurses / Pharmacy staff
- Responsible for: clearly completing the ADR form and submitting it to either the Pharmacist, Pharmacists Assistant (PA) or Facility Manager
- Required:
  - Standardized ADR forms to be easily available
  - Training of and feedback to clinicians / nurses / pharmacy staff

### Role of Pharmacists Assistant (PA) / Facility Manager
- Responsible for:
  - Collection of completed ADR forms and submission to Managers: Pharmaceutical Services [either hospital /district]
- Required:
  - *Fax / scanning functionality and email*

### Responsibility of: Managers: Pharmaceutical Services [either hospital /district] assisted by a Post Basic Pharmacists Assistant
- Responsible for:
  - Ensuring accurate capture of ADR forms in standardized database
  - Provision of stats on numbers of ADR reported to respective management
  - Submission of all submitted ADR forms and data base to Medicines Information Centre [MIC] by the 21st of each month: fax 021 448 0503
  - Submission of all ADR forms to NADEMEC fax: 021 448 6181
  - Reporting of ADRs to respective district/institution PTC's for discussion
  - Distribution of the quarterly and annual report to relevant management; clinical staff; PTC's, SSA's
- Required:
  - Standardized data base [interim excel or access]
  - Training of and feedback to PA's regarding accuracy of capturing

### Responsibility of: Medicines Information Centre [MIC]
- Responsible for:
  - Individual feed back to submitting health professionals (time dependant)
  - Evaluation of top 10 medicines / top 10 ADR / high risk ADR's [causality]
  - Provision of draft quarterly/annual report to PPTC for input / action decisions
- Required:
  - Skilled Pharmacist
  - Signed SLA
  - Import of databases into management database

### Responsibility of: Provincial Pharmacy Services; PPTC; Policy advisory groups [HAST]; Health Programmes; Family Physicians; district and hospital PTC's; HIA; PHC managers; Manager Pharmaceutical Services.
- Responsible for:
  - PPTC: Analyse draft quarterly and annual reports provided by MIC; and make recommendations for further actions, if required
  - PS: Finalise reports with necessary recommendations and distribute to policy advisory groups; family physicians; district and hospital PTC's; HIA; PHC managers; Managers: Pharmaceutical Services and HAST directorate
  - Health Programmes: amend policy / guidelines accordingly
  - Service delivery level: ensuring policy/guideline amendments are affected
- Required:
  - Effective communication channels

Amended by: Western Cape Government Pharmacy Services: May 2013
Appendix 6: Data Collection Tools

A. Demographic questions

For each question mark only one response unless otherwise indicated.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>2. Age</td>
<td></td>
</tr>
<tr>
<td></td>
<td>years</td>
</tr>
<tr>
<td>3. Race</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td></td>
</tr>
<tr>
<td>Coloured</td>
<td></td>
</tr>
<tr>
<td>Indian</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Specify:______________</td>
</tr>
<tr>
<td>Chose not to answer</td>
<td></td>
</tr>
<tr>
<td>4. Mother tongue language</td>
<td></td>
</tr>
<tr>
<td>Afrikaans</td>
<td></td>
</tr>
<tr>
<td>English</td>
<td></td>
</tr>
<tr>
<td>isiNdebele</td>
<td></td>
</tr>
<tr>
<td>IsiXhosa</td>
<td></td>
</tr>
<tr>
<td>isiZulu</td>
<td></td>
</tr>
<tr>
<td>Sesotho</td>
<td></td>
</tr>
<tr>
<td>Sesotho sa Leboa</td>
<td></td>
</tr>
<tr>
<td>Language</td>
<td>Select</td>
</tr>
<tr>
<td>--------------</td>
<td>--------</td>
</tr>
<tr>
<td>Setswana</td>
<td></td>
</tr>
<tr>
<td>siSwati</td>
<td></td>
</tr>
<tr>
<td>Tsivenda</td>
<td></td>
</tr>
<tr>
<td>Xitsonga</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Specify: ____________________</td>
</tr>
</tbody>
</table>

5. Education
(Mark response for both 5a) and 5b)

5a) Highest pharmacy qualification obtained
- Bachelors degree
- Masters degree
- Doctorate

5b) Other post-graduate qualifications, if applicable
Specify: ____________________

6. Employment
(Mark response for 6a) and 6b)

6a) Number of years of practice as pharmacist ________ years

6b) Current position
- Pharmacy Manager
- Supervisor Pharmacist
- Production Pharmacist
- Community Service Pharmacist
- Intern Pharmacist
- Other Specify: ____________________
<table>
<thead>
<tr>
<th>6c) Previous experience <em>(mark all that apply)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Community Pharmacy</td>
</tr>
<tr>
<td>Consultant Pharmacy</td>
</tr>
<tr>
<td>Manufacturing Pharmacy</td>
</tr>
<tr>
<td>Private Institutional Pharmacy</td>
</tr>
<tr>
<td>Public Institutional Pharmacy</td>
</tr>
<tr>
<td>Wholesale Pharmacy</td>
</tr>
<tr>
<td>Provider of Education and Training</td>
</tr>
<tr>
<td>Other Specify:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Adverse Drug Reaction reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>7a) At least one ADR reported in professional career?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No <strong>End of form</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7b) Estimated number of ADRs reported in professional career</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – 5</td>
</tr>
<tr>
<td>5 – 10</td>
</tr>
<tr>
<td>&gt;10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7c) Date last ADR reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month – Year</td>
</tr>
</tbody>
</table>
B. **Pharmacist Semi-structured Interview Schedule**

1. What do you think is the pharmacist’s role in reporting ADRs?
   
   Probe: Who’s responsibility? Part of pharmaceutical care role? Can you identify an ADR? Did you come across an ADR? How important is it to report an ADR? Have you reported ADRs?

2. Please describe the ADR reporting process in your District?
   
   Probe: When should one report? Where to one find ADR forms?
   
   Do you ever receive feedback on the report that was submitted?

3. What are the barriers to reporting ADRs in this district?
   
   Probe: workload? Complexity of system? Feedback?

4. What would facilitate increased reporting of ADRs in this district?

C. **Key Stakeholder Semi-structured Interview Schedule**

1. Please describe the ADR reporting process in the Western Cape Province?

2. How easy is it to report an ADR in the public sector?

   (the new circular that was issued recently, do you think that that will facilitate more reporting?)

3. What would you say is the role of pharmacists in the reporting of ADRs?

4. What do you think is needed for pharmacists to report more ADRs?

   (What would you say is more needed to report at facility level?)

5. What would you say are the barriers in reporting more ADRs?
Appendix 7: Ethics Committee Approval Letter

OFFICE OF THE DEAN
DEPARTMENT OF RESEARCH DEVELOPMENT

UNIVERSITY OF THE WESTERN CAPE

05 December 2012

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape has approved the methodology and ethics of the following research project by:
Mr C Williams (School of Public Health)

Research Project: Perceptions and experiences of reporting of adverse drug reactions by public sector pharmacists in a rural district in the Western Cape.

Registration no: 12/10/31

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Jostus
Research Ethics Committee Officer
University of the Western Cape
Appendix 8: Participant Information Sheet

UNIVERSITY OF THE WESTERN CAPE

School of Public Health
Private Bag X 17, Bellville 7535, South Africa
Tel: +27 21-9592800, Fax: +27 21-9592872
http://www.soph.wvc.ac.za

Participant Information Sheet

TITLE OF RESEARCH: Reasons for under-reporting of Adverse Drug Reactions by pharmacists in the public sector in a rural district in the Western Cape Province, South Africa.

Dear Participant

You are being invited to take part in a research project. The research is being conducted for a mini-thesis, which is a requirement for the Masters in Public Health, which I am completing at the University of the Western Cape.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take your time to decide whether or not you wish to take part in this research.

My contact details and those of my supervisor are recorded at the end of this memo.

PURPOSE OF THE STUDY
This study proposes to explore and describe perceptions and experiences of public sector employed pharmacists regarding the under-reporting of Adverse Drug Reactions in the Cape Winelands District.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to participate in this study, it will involve myself conducting an individual interview with you. I will ask you about your experiences, ideas, opinions and role concerning the reporting of Adverse Drug Reactions in your setting. During the interview, I will be taking notes of our discussion and will use a Digital tape recorder in order to adequately collect all the information that is needed for the study.

A WHO Collaborating Centre for Research and Training in Human Resources for Health
CONFIDENTIALITY
Your name will not be recorded during the interview so as to maintain confidentiality at all times. I shall keep all records and tapes of your participation, including a signed consent form which I will need from you should you agree to participate in this research study, locked away at all times and will destroy them after the research is completed.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this research is entirely voluntary i.e. you are free to decline participation. It is up to you to decide whether or not to take part. Refusal to take part will involve no penalty or loss of benefits to which you are otherwise entitled (as an employee of the state) and it will not affect negatively on your position as a staff member working in your institution.
If you do decide to take part, you will be given this information sheet to keep (and be asked to sign a consent form). If you decide to take part, you are still free to withdraw at any time - and without giving a reason. You may also choose not to answer particular questions that are asked in the study. If there is anything that you would prefer not to discuss, please feel free to say so.

BENEFITS AND COSTS
You may not get any direct benefit from this study. While there are no immediate direct benefits to those participating in the study, the information we learn from you may help in making recommendations to strengthen the ADR spontaneous reporting system in the Cape Winelands District. There are no costs for participating in this study other than the time you will spend in the interview, which will last approximately 30 to 40 minutes. The interviews will be conducted at your place of work.

INFORMED CONSENT
Your signed consent to participate in this research study is required before I proceed to interview you. I have included the consent form with this information sheet so that you will be able to review the consent form and then decide whether you would like to participate in this study or not.
CIRCULAR H181/2013

TO:  DDG: CHIEF OF OPERATIONS
     CHIEF DIRECTORS
     DIRECTORS
     HEADS OF INSTITUTIONS
     DEPUTY DIRECTOR: CAPE MEDICAL DEPOT
     HEAD OF HEALTH: CITY OF CAPE TOWN
     RESPONSIBLE PHARMACIST: CHRONIC DISPENSING UNIT UTI

N.B. FOR CIRCULATION TO ALL MEDICAL, PARAMEDICAL, PHARMACEUTICAL AND NURSING PERSONNEL

PHARMACEUTICAL CODE LIST: SUPPLEMENTARY LIST NO. 131

1. Attached is Supplementary List No. 131 of amendments to the Provincial Government: Western Cape’s Pharmaceutical Code List.

2. Kindly change, where applicable, the Code List in your possession.

3. Failure to comply with the Code List will be regarded in a very serious light and may lead to even more severe restrictions on the use of pharmaceuticals.
4. Patients cannot be referred from one hospital to another on medicine not in the Code List. Patients must be referred according to the system described in Circular H 23 / 2012 dated 20 February 2012.

5. Queries or problems with regard to this supplementary list are all to be addressed to The Head: Department of Health, for attention, The Director: Pharmacy Services.

6. Please note that medical personnel that are registered as specialists in that discipline may only prescribe items marked for a specific speciality. For example, Urologists may not prescribe items restricted to Ophthalmologists.

Ms K Lowenherz
DIRECTOR: PHARMACY SERVICES
DATE: 11/13

UNIVERSITY of the WESTERN CAPE
### SUPPLEMENTARY LIST NO. 131

#### ANNEXURE A:
Preparations approved for addition to the **General** category in the WCGH Code List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrofurantoin capsules 50mg and 100mg</td>
<td>Macrodantin</td>
<td>16.4 Urinary agents: Urinary antiseptics</td>
<td></td>
</tr>
<tr>
<td>Venapamil tablets 240mg</td>
<td>Isoptin</td>
<td>7.3.7 CVA: Calcium channel blockers</td>
<td></td>
</tr>
<tr>
<td>Azithromycin injection 500mg</td>
<td>Zithromax</td>
<td>18.2 Anti-microbials: Erythromycin and other macrolides</td>
<td>Cheapest macrolide on tender to be used. Severe pneumonia (switch to oral macrolide as soon as patients improve. Cheapest macrolide on tender to be used – currently erythromycin.) Endoscopy units for H.Pylori. Not to be used for MOTT.</td>
</tr>
</tbody>
</table>

#### ANNEXURE B:
Preparations approved for addition to the **Specialist Initiated** category in the WCGH Code List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
</table>

#### ANNEXURE C:
Preparations approved for addition to the **Specialist** category in the WCGH Code List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
</table>

---

Supplementary List 131: Circular No. 2013 – October 2013
### ANNEXURE D:
Preparations approved for addition to the **Patient Name Basis** category in the WCCH Code List (for academic hospitals only)

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbimazole tablets 5mg</td>
<td>Neo-mercazolol</td>
<td>19.3 Endocrine system: Thyroid</td>
<td>Specialist initiated</td>
</tr>
<tr>
<td>Tramadol tablets 50mg</td>
<td>Tramal, Tramazol</td>
<td>3.4 Analgesics: Others</td>
<td>General</td>
</tr>
<tr>
<td>Magnesium trisilicate suspension</td>
<td></td>
<td></td>
<td>Specialist initiated</td>
</tr>
<tr>
<td>Losartan tablets 50mg and 100mg</td>
<td>Los-Arb, Cipla Losartan</td>
<td>7.3.9 Cardiovascular agents: Angiotensin receptor antagonists</td>
<td>Specialist initiated</td>
</tr>
<tr>
<td>Clarithromycin injection 500mg</td>
<td>Klicid</td>
<td>18.2 Anti-microbials: Erythromycin and other macrolides</td>
<td>Specialist</td>
</tr>
<tr>
<td>Vaccine pneumococcal, polyvalent 0.5ml</td>
<td>Pneumovax-23; Innovax pneumo 23</td>
<td>26 Biologicals</td>
<td>General</td>
</tr>
</tbody>
</table>

### ANNEXURE E:
Preparations **reclassified or conditions for use altered** in the WCCH Code List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>AMENDED CODING CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbimazole tablets 5mg</td>
<td>Neo-mercazolol</td>
<td>19.3 Endocrine system: Thyroid</td>
<td>Specialist initiated</td>
<td>As add-on therapy to paracetamol. Recommended dose 50mg six hourly. Not repeatable for acute conditions (short course).</td>
</tr>
<tr>
<td>Tramadol tablets 50mg</td>
<td>Tramal, Tramazol</td>
<td>3.4 Analgesics: Others</td>
<td>General</td>
<td>HIV associated peripheral neuropathy as second or third line (may be used without paracetamol). Repeatable.</td>
</tr>
<tr>
<td>Magnesium trisilicate suspension</td>
<td></td>
<td></td>
<td></td>
<td>For neuropathic pain as second or third line (may be used without paracetamol). Prescription must be endorsed “neuropathic pain”. Refer to SL 111.</td>
</tr>
</tbody>
</table>
| Losartan tablets 50mg and 100mg | Los-Arb, Cipla Losartan | 7.3.9 Cardiovascular agents: Angiotensin receptor antagonists | Specialist initiated | For ACEI intolerant patients. Max dose: 100mg daily. NOTE: ARB’S are contraindicated in patients with angioedema on ACEI.
| Clarithromycin injection 500mg | Klicid | 18.2 Anti-microbials: Erythromycin and other macrolides | Specialist | On patient name basis in tertiary hospitals for MOTT (mycobacterium other than tuberculosis). |
| Vaccine pneumococcal, polyvalent 0.5ml | Pneumovax-23; Innovax pneumo 23 | 26 Biologicals | General | Asplenic patients and patients with chronic cerebrospinal fluid leaks. |
### ANNEXURE F:
Preparations approved for use by Special Programmes to be added to the WCGH Code List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
</table>

### ANNEXURE G:
Preparations temporarily approved for investigation in terms of efficacy, safety, cost, etc, to be added to the WCGH Code List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
</table>

### ANNEXURE H:
Preparations approved for deletion from the WCGH Code List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verapamil tablets 80mg</td>
<td>Lisopin</td>
<td>7.3.7 CVA: Calcium channel blockers</td>
<td>Discontinued. Verapamil 40mg and 240mg available.</td>
</tr>
<tr>
<td>Probenecid tablets 500mg</td>
<td>Proben</td>
<td>4.2 Musculo-skeletal agents: Anti-gout</td>
<td>Not on EML. Problems with availability.</td>
</tr>
<tr>
<td>Malic acid + benzoic acid + salicylic acid + propylene glycol cream 0.375% + 0.025% + 0.008% + 1.75%</td>
<td>Aserbine</td>
<td>14.9 Dermatologicals: Others</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**NOTE:** ALL CAPE MEDICAL DEPOT ITEMS DELETED ARE STILL TO BE USED UNTIL STOCKS ARE DEPLETED.

### ANNEXURE I:
Preparations evaluated but not approved / accepted for addition to the WCGH Formulary List

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>MOTIVATION PRESENTED BY</th>
<th>REMARKS</th>
</tr>
</thead>
</table>

*Supplementary List 131: Circular H/181/013 – October 2013*
ANNEXURE J:

Corrections to previous Code List: None

<table>
<thead>
<tr>
<th>GENERIC DESCRIPTION</th>
<th>COMMON TRADE NAME</th>
<th>CLASSIFICATION</th>
<th>REMARKS</th>
</tr>
</thead>
</table>

ADDENDUM A: LOW MOLECULAR WEIGHT HEPARIN (LMWH) CODING POLICY
WESTERN CAPE GOVERNMENT HEALTH
CODING STATUS: LOW MOLECULAR WEIGHT HEPARIN (LMWH) USE

ADDENDUM A

Available:
Enoxaparin Sodium 40mg, 60mg and 80mg pre-filled injections are available.

RECOMMENDED DOSES FOR ADULTS

Prophylactic use:
- Deep Vein Thrombosis (DVT): Surgical patients:
  40mg s.c. 12 hours pre-op and 12 hours post-op, and thereafter once daily for up to 31 days in orthopaedic surgery (hip or knee replacement surgery) patients and until ambulatory in other surgery patients.
- Venous Thromboembolism (VTE): Patients bed ridden due to debilitating medical illnesses; with a significant risk for DVT or VTE:
  40mg s.c., once daily until ambulant.
- Pregnant patients with previous proven DVT or VTE on warfarin:
  Prophylactic dose: Swop from warfarin to enoxaparin 1mg/kg 12 hourly for 8 weeks, followed by 40mg 12 hourly until 20 weeks gestation or 2 weeks before elective delivery; and post-partum 40mg daily for 1 week while being converted to warfarin.

Treatment:
- Acute Coronary Syndrome
  Treatment dose: 1mg/kg 12 hourly for 3 days.
- DVT/ Pulmonary Embolism
  Treatment dose: 1mg/kg 12 hourly for 5-7 days until INR stable.
- Pregnant patients with prosthetic heart valves:
  Treatment dose 1mg/kg 12 hourly. The dose should be adjusted according to anti-Xa results. This usage can only be allowed if the dose can be titrated against the anti-Xa assays. The anti-Xa assay is currently available at the Red Cross Children’s Hospital by the National Health Laboratories Service (NHLS).

Anti-Xa assay
Indicated in the following patients receiving treatment or prophylactic doses to titrate enoxaparin dose:
- Morbidly obese patients: BMI > 40 or patients with a body weight >100 kg
- Low-weight women (< 45 kg) and low-weight men (< 57 kg)
- Patients with renal impairment: estimated creatinine clearance < 30ml/min

The anti-Xa assay is currently provided at the Red Cross Children’s Hospital by the National Health Laboratories Service (NHLS). Take 5 ml of citrated blood 3 hours after the 3rd dose of enoxaparin. Contact the Coagulation Laboratory on 021 938 4615 (THM) or 021 404 3191 (GSH) before taking the sample to ensure rapid sample processing. Target levels: prophylactic LMWH 0.3 - 0.5 anti-Xa units/ml, therapeutic LMWH 0.6 - 1.0 anti-Xa units/ml. Pregnant patient with artificial cardiac valve receiving therapeutic LMWH 1.0 - 1.2 anti-Xa units/ml.

NOTE:
- No dose of enoxaparin will be issued without the patient’s body weight and diagnosis of prophylaxis or treatment having been written on the prescription.
- Stop enoxaparin at least 12 hours before any procedure.
- In the case of mg/kg dosing recommendations, dose according to weight and not rounded off to the nearest dose package.

Updated by the Western Cape Provincial Pharmacy and Therapeutics Committee
September 2013

Supplementary (A131): Circular H181/2013 – October 2013 – Addendum A

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APPENDIX 10: CAPE WINELANDS DISTRICT PHARMACEUTICAL VERIFICATION TEMPLATE

![Image]

**PHARMACEUTICAL SERVICES - VERIFICATION REPORT - CLINICS**

<table>
<thead>
<tr>
<th>ADMINISTRATION &amp; SERVICE DELIVERY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Security</strong></td>
</tr>
<tr>
<td>1. Does only the pharmacist and assistant/operational manager have access to the keys of the pharmacy/medicine room?</td>
</tr>
<tr>
<td>2. Is there adequate security to prohibit the unauthorized access to medication in the medicine and consultation rooms?</td>
</tr>
<tr>
<td><strong>Stock location</strong></td>
</tr>
<tr>
<td>3. Is the stock in the medicine room kept under neat &amp; clean conditions?</td>
</tr>
<tr>
<td>4. Are medicines stored in groups, alphabetically according to generic names?</td>
</tr>
<tr>
<td>5. Is stock kept on the floor?</td>
</tr>
<tr>
<td>6. Is pharmaceutical and non-pharmaceutical stock stored separately?</td>
</tr>
<tr>
<td>7. Is the temperature in the medicine and medicine consultation rooms kept below 20°C, as controlled and recorded by a thermometer?</td>
</tr>
</tbody>
</table>

**Orders**

| 8. Is the correct ordering procedure followed, i.e. Regulation with 2 different signatures? | | | |
| 9. Are clinic order forms filled in completely eg stock on hand, etc? | | | |
| 10. Are regular, evenly spaced, orders placed? Monthly or weekly? | | | |
| 11. Are the invoices reconciled with the CMO computer print out to enable the follow up of non-completed orders? | | | |
| 12. Are orders (requisition or clinic order form), delivery notes and invoices filed systematically? | | | |
| 13. Are all the SOPs, the latest editions of the EML, MMR, SAWF and GPP available and are procedures followed? | | | |
| 14. Does labelling comply with requirements? | | | |
| 15. Are statistics complete and submitted on time? | | | |

**Total for Administration and Service Delivery**

<p>| 30 | % |</p>
<table>
<thead>
<tr>
<th>STOCK CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receipt</strong></td>
</tr>
<tr>
<td>1. Is stock checked upon receipt to confirm correct items, quality, quantity and expiry dates?</td>
</tr>
<tr>
<td>2. Is stock checked against the invoice and signed upon receipt?</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
</tr>
<tr>
<td>3. Is stock handled according to FIFO and FEFO principles?</td>
</tr>
<tr>
<td>4. Are stockcards used?</td>
</tr>
<tr>
<td>5. Are all movements of stock recorded on the stock card?</td>
</tr>
<tr>
<td>6. Does the open stock exceed more than 2 weeks stock?</td>
</tr>
<tr>
<td>7. Is stock verification according to the stockcards correct? (Review 10 cards)</td>
</tr>
<tr>
<td>(Review 10 cards)</td>
</tr>
<tr>
<td>7.1</td>
</tr>
<tr>
<td>7.2</td>
</tr>
<tr>
<td>7.3</td>
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<tr>
<td>7.4</td>
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<td>7.5</td>
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<tr>
<td>7.6</td>
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<tr>
<td>7.7</td>
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<tr>
<td>7.8</td>
</tr>
<tr>
<td>7.9</td>
</tr>
<tr>
<td>7.10</td>
</tr>
<tr>
<td>8. Are stock levels determined according to the presented guidelines and recorded on stockcards? (Review 10 cards)</td>
</tr>
<tr>
<td>Question</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Are the re-order levels and minimum levels adjusted 6 monthly? See evidence.</td>
</tr>
<tr>
<td>Are Schedule 5 medications secured and stored in a lockable cabinet?</td>
</tr>
<tr>
<td>Are Schedule 5 medicines recorded on a patient name basis in the schedule register?</td>
</tr>
<tr>
<td>Is the Schedule 5 register's recordings up to date?</td>
</tr>
<tr>
<td>Does the medication stored in the consultation rooms comply with all the requirements as stipulated in the GMP?</td>
</tr>
<tr>
<td>Is the emergency trolley found to be organised and ready? (CRITICAL POINT)</td>
</tr>
<tr>
<td>Is the emergency trolley found to be complete, and if not what should be added? (CRITICAL POINT)</td>
</tr>
<tr>
<td>Are there any expired medication found on the emergency trolley? Specify what is expired. (CRITICAL POINT)</td>
</tr>
<tr>
<td>Is expired stock handled correctly? (Sent for destruction and recorded?) See documentation as evidence.</td>
</tr>
<tr>
<td>Is there any expired stock on the shelf and is expired and damaged stock stored separately?</td>
</tr>
<tr>
<td>Is excess stock handled correctly? (Redistributed or sent for redistribution?) See documentation as evidence.</td>
</tr>
<tr>
<td>Is there a system for the correct handling of medication not collected by patients and is this recorded on the prescription?</td>
</tr>
<tr>
<td>Issuing</td>
</tr>
<tr>
<td>Do prescriptions comply with the regulatory requirements e.g. Genetic names, prescribers' names etc on prescriptions or in pharmacy and are prescriptions rewritten/reviewed 6 monthly? (Circular 142 / 2006)</td>
</tr>
<tr>
<td><strong>Total for Stock Control</strong></td>
</tr>
<tr>
<td>COLD CHAIN CONTROL - 5 Points each</td>
</tr>
<tr>
<td>-----------------------------------</td>
</tr>
<tr>
<td>1. Is the temperature chart located at the fridge and is it completed daily? (between 2°C and 8°C)</td>
</tr>
<tr>
<td>2. Is there a functioning thermometer in the fridge?</td>
</tr>
<tr>
<td>3. Are there any vaccines out of stock?</td>
</tr>
<tr>
<td>4. Are any vaccines left to be expired?</td>
</tr>
<tr>
<td>5. Are the fridge sealed according to EP procedures / guidelines?</td>
</tr>
<tr>
<td>6. Are there stockcards for the vaccines?</td>
</tr>
<tr>
<td>7. Are all movements of vaccines recorded on the stock card?</td>
</tr>
<tr>
<td>8. Are the stock cards up to date?</td>
</tr>
<tr>
<td>9. Is the fridge clean and dust-free and is it used for vaccines only?</td>
</tr>
<tr>
<td>10. Is there an emergency plan and a cleaning schedule located at the fridge?</td>
</tr>
<tr>
<td>11. Is the open vial policy applied and are all open vials dated correctly?</td>
</tr>
<tr>
<td>12. Is the cold chain maintained: Vaccines not frozen and VVMs found in good order?</td>
</tr>
<tr>
<td>13. Is the &quot;power failure report&quot; available and where applicable, completed?</td>
</tr>
</tbody>
</table>

Total for Cold Chain Control: 65
## TRACER MEDICINE

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Adequate - 0</th>
<th>Adequate - ½</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adrenalin 1mg injection</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-trimoxazole 50 of 100mg suspension</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTP (IPV/Hib) (Pentavalent vaccine)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethambutol, Rifampicin, Isoniazid and Pyrazinamide tab, 279/150/75/400</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metformin 500mg of 850mg tablets</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nevirapine 10mg/ml solution</td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Panzololol 500mg tablets</td>
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<tr>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Sodium Chloride 0.9% 1 liter</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Zidovudine 500mg tablets</td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>National Core Standards</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin in caps</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin sup.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefoxime / Cefuroxim tab.</td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocortisone tab.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin (any pack size or formulation)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norethisterone or Medroxyprogesterone 5mg (Not Lactating or Postmenopausal)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Rehydration Salt (Gastrolyte)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol sup.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salbutamol inhaler</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VI A capsules</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>TB Medicine</strong></td>
<td></td>
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<td></td>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Ethambutol tab</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isoniazid 100mg (INH) tab.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isoniazid 300mg (INH) tab.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifampicin and Isoniazid tab 500mg Pred</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifampicin and Isoniazid tab 150mg/75</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifampicin and Isoniazid tab 300mg/150</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARV Sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Anti-retrovirals used for the standard anti-retroviral regimen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post Exposure Prophylaxis</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Syphilis</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis Test Strips</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IMCI</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole / Mebendazole tabl.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceftriaxone amp.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-trimoxazole tabl.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dapsone inj.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ferrous gluconate syrup</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisone tabl.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total for Tracer, National Core Standards on IMCI Medicines: 18%

Grand Total: 180%

I, the undersigned, declare that I will immediately give attention to all critical points and that I will provide feedback within one week of the verification visit, on the correction of these points, to the Primary Healthcare Manager and the District Office Pharmaceutical Services.

Pharmacist/Assistant

Verification Officer

Sister in Charge