A REVIEW OF THE SOUTH AFRICAN PHARMACY LICENCE APPROVAL PROCESS AND RELEVANT STAFF PERCEPTIONS OF THE TASK AND PROCESS

A dissertation submitted by

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in partial fulfilment of the requirements for the degree

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in the

Faculty of Health Sciences

(School of Health Care Sciences)

at the

University of Limpopo (Medunsa Campus)

Department of Pharmacy

Supervisor: Professor RS Summers

Co-supervisor: Ms E Helberg

2014
DECLARATION

I, Ms Daphney Fafudi, declare that the dissertation hereby submitted to the University of Limpopo, Medunsa Campus, for the degree of Master of Science (Medicine) Pharmacy, in the Faculty of Health Sciences, School of Health Care Sciences, has not previously been submitted by me for a degree at this or any other university; that it is my work in design and execution, and that all material contained herein has been duly acknowledged.

__________________________________  __________________
Fafudi, D (Ms)                      Date
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- My Family. In particular my husband: Tebogo Brian Fafudi and mother Mrs Lilly Monyeseale
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<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ACPA:</td>
<td>Australian Community Pharmacy Authority</td>
</tr>
<tr>
<td>BPR:</td>
<td>Business Process Reengineering</td>
</tr>
<tr>
<td>Days:</td>
<td>Calendar days</td>
</tr>
<tr>
<td>DCI:</td>
<td>Data Collection Instruments</td>
</tr>
<tr>
<td>DG:</td>
<td>Director General</td>
</tr>
<tr>
<td>EC:</td>
<td>Eastern Cape</td>
</tr>
<tr>
<td>FS:</td>
<td>Free State</td>
</tr>
<tr>
<td>GMP:</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>GP:</td>
<td>Gauteng Province</td>
</tr>
<tr>
<td>GPP:</td>
<td>Good Pharmacy Practice</td>
</tr>
<tr>
<td>GWDP:</td>
<td>Good Wholesale and Distribution Practice</td>
</tr>
<tr>
<td>IT:</td>
<td>Information Technology</td>
</tr>
<tr>
<td>KZN:</td>
<td>Kwa-Zulu Natal</td>
</tr>
<tr>
<td>LP:</td>
<td>Limpopo</td>
</tr>
<tr>
<td>MCC:</td>
<td>Medicines Control Council</td>
</tr>
<tr>
<td>MIS:</td>
<td>Management Information System</td>
</tr>
<tr>
<td>MP:</td>
<td>Mpumalanga</td>
</tr>
<tr>
<td>MREC:</td>
<td>Medunsa Research and Ethics Committee</td>
</tr>
<tr>
<td>MUSA:</td>
<td>Medicine Usage in South Africa</td>
</tr>
<tr>
<td>NC:</td>
<td>Northern Cape</td>
</tr>
<tr>
<td>NDoH:</td>
<td>National Department of Health</td>
</tr>
<tr>
<td>NDP:</td>
<td>National Drug Policy</td>
</tr>
<tr>
<td>NW:</td>
<td>North West</td>
</tr>
</tbody>
</table>
PSSA: Pharmaceutical Society of South Africa
SA: South Africa
SAPC: South African Pharmacy Council
SOPs: Standard Operating Procedures
Stats SA: Statistics South Africa
TQM: Total Quality Management
USA: United States of America
WC: Western Cape
ABSTRACT

Background:

The National Department of Health (NDoH) and the South African Pharmacy Council (SAPC) are currently jointly responsible for the approval and registration of pharmacy premises licences, among numerous other activities. These two entities consider applications for such licences and, if the applications are acceptable, issue the respective licence. The issue of these licences is of public concern as access to pharmaceutical services is referred to in both the Constitution of South Africa and in the National Drug Policy (NDP).

Since the process of pharmacy licence approval is governed by guidelines and standards, it is important to determine whether the NDoH and the SAPC adhere to the Standard Operating Procedures (SOPs) and guidelines when they handle applications and whether the respective processes expedite access to pharmaceutical care in the public interest.

Aim of study:

To describe the service for pharmacy premises licence approval during the period 01 January, 2012 to 31 December, 2012, and to determine the perceptions about the task and processes held by involved staff (at the NDoH and the SAPC).

Objectives:

The objectives of the study were to:
1. document and carry out a critical review of the steps involved in processing applications for pharmacy premises licences;
2. determine whether the application process complies with the current SOPs and guidelines for pharmacy premises licence approval;
3. identify the factors which cause deviations from the SOPs and guidelines for pharmacy premises licence approval;
4. describe the perceptions of the task and processes of involved staff (at the NDoH and the SAPC);
5. identify whether the process of pharmacy premises licence approval ensures an optimal response to the country’s needs in terms of access to pharmaceutical care.
Method:

Data for the study were collected by retrospective record review and a self-administered questionnaire and were captured and manually categorised. The study was conducted at the NDoH and the SAPC offices in Pretoria. Data collection commenced after approval was granted by the Medunsa Research Ethics Committee (MREC), the NDoH and the SAPC.

The study population included all pharmacy premises licence applications received during the period 01 January, 2012 to 31 December, 2012, 404 in total. After cleaning the data, the remaining applications numbered 325. All staff working with 2012 pharmacy premises licence approval at both the NDoH and the SAPC, and who had signed informed consent statements, were included in the study (20 participants).

Relevant data were collected from databases at NDoH and SAPC between April and August 31, 2014 and through a questionnaire responded to by the relevant staff. Data were captured by the researcher on a Microsoft Excel™ spread sheet and were checked for accuracy and completeness repetitively. Data were also cross-checked for accuracy and completeness in SAS, Release 9.2, running on Microsoft Windows Vista MIS. All information was treated as confidential and all identities remained anonymous.

Results:

Results were presented in tables and charts and covered the following matters.

- Evaluation of applications categorised by province, ownership, application type and sector.
- Duration of Good Pharmacy Practice (GPP) processing application per step (per person).
- Number of resubmissions in line with the SOP.
- Summary of staff perceptions.
- Summary of the overall processing of applications and whether they complied or not, based on the viable measures used.

Data for 325 pharmacies were evaluated. The time periods required for the licence approval procedure far exceeded the designated times. The average time spent in GPP evaluation by the SAPC was 252 days compared with the 42 days specified in the Standard Operating Procedures. The average overall time spent from receiving an application at NDoH to
finalisation was 307 days. Data were presented by province, ownership application type and sector. The times taken for each staff member to carry out his/her responsibilities and the number of applications and events involved in the process are also presented. A degree of uncertainty about responsibilities and priorities of the involved staff was identified, as well as some procedural concerns.

SAPC staff mentioned that they do not consider this task a priority and applications were likely not to be processed on first come/first served basis as a result. They highlighted that the task would be better performed and expedited by one organisation, with one set of resources (cost-effectiveness) and accountability (better prioritised). In countries such as Kenya, Ghana and the United States of America one organisation, which is usually the Pharmacy Council/Board, carried out the task.

Concerns for both NDoH and SAPC staff included that the existing criteria/standards for evaluation are not clear and are given different interpretations by individual staff members as well as the applicants. More than three cycles of GPP evaluation by practitioners and managers at SAPC occurred. The NDoH recorded sending 315 of 325 evaluated applications to the SAPC, but the SAPC manual records had 304 instead of 325 which was evaluated electronically. Of the 325 SAPC evaluated applications 292 were evaluated at least twice with reasons being site/floor plans that did not comply with criteria. More than 90% of applications were not approved on the first submission. The delays in the current approval processes carried high risks of potential pharmacies not opening, especially those with limited resources, due to costs such as premises leasing, staff recruitment and retention while awaiting approval.

**Conclusions:**

The NDoH and the SAPC do not fully adhere to their SOPs and guidelines when processing pharmacy premises licence applications, which results in unacceptable delays and costs for the applicants. This situation may result in the profession and the public possibly losing confidence in the regulations of this service. It also impacts negatively on the objectives of NDoH and SAPC in focussing on the public interest by reducing access to pharmaceutical services. The key reason for the existence of the SAPC is to regulate pharmacy education and practice. Pharmacy practice starts at the licensed pharmacy. No pharmacy licence means no pharmacy, pharmacist, pharmacy support personnel, training of personnel and no access of pharmaceutical care to the public. A delay of a pharmacy licence also means a delay of access to care.
Recommendations

1. The NDoH and the SAPC need to work together to develop clear guidelines/criteria for the site/floor plan requirements. These matters must be known and understood by all relevant staff and stakeholders to avoid non-compliance of 90% of applications on first submissions.

2. The criteria must rigorously address the concern of maldistribution in concentration of pharmacies in urban areas and continued scarcity in rural areas.

3. The process should assist the applicants by confirming whether shortcoming letters were received and where necessary a phone call should be made to explain the shortcomings with them.

4. One organisation must perform this task to shorten the process and maximise the optimal use of resources. The Management Information System (MIS) at SAPC is commendable and has consistent records.

5. If 4, above is not possible, a cost recovery exercise with a reviewed cost- and time-effective process should be performed at NDoH and SAPC.

6. Regular monitoring and evaluation of this task should be done by management (possibly weekly reviews initially for a while to ensure that the process is fully achievable and implemented in the stipulated time).

7. Sufficient people should be assigned or employed to specialise on this task. This is applicable to the SAPC as they use the "round-robin" system to allocate different applications to staff.

8. Advocacy for the establishment of rural pharmacies is essential, particularly amongst Companies - as one of the reasons of opening pharmacy ownership to lay persons was to have a fair distribution of pharmacies in South Africa with more pharmacies in rural areas.

9. Applications must be finalised using the first come/first served principle with the exception of rural applications which must get additional focus and effort. Implementation should be audited.
CHAPTER 1
INTRODUCTION

1.1 BACKGROUND

The NDoH in collaboration with the SAPC, in terms of the Pharmacy Act, 1974 (Act No. 53 of 1974), considers pharmacy premises licence applications and, if approved, issues the necessary licences. The approval of pharmacy premises licence applications is one of the key services offered by the NDoH and the SAPC as it has an impact on national health outcomes, e.g. access to essential medicines by the South African public as referred to in the Constitution of South Africa (NDoH, 1996a) and the NDP (NDoH, 1996b). Hence the task must be performed effectively and efficiently.

Thomas (2010) stated that for an organisation to succeed it must continually improve its processes, reassess its ability to meet customer needs, and gather customer data to keep well appraised of their changing needs and expectations. In this case the customer is the public.

For 2013, Statistics South Africa (Stats SA, 2013) estimated the mid-year population at 52,98 million and 49,32 million for 2011. The estimated overall growth increased by approximately 1,34% in 2012–2013 (Stats SA, 2013). In October, 2014 there was a total of 4,389 active pharmacies with 4,304 in 2011. The increase for the period 2011 to 2014 was 85 active pharmacies (See Tables 1.1, 1.2 and 1.3). The average annual increase from 2011 to date was 28.

Table 1.1: Distribution of pharmacies by sector and province on 30 October, 2014

<table>
<thead>
<tr>
<th>Pharmacy sector</th>
<th>EC</th>
<th>FS</th>
<th>GP</th>
<th>KZN</th>
<th>LP</th>
<th>MP</th>
<th>NW</th>
<th>NC</th>
<th>WC</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community Pharmacy</td>
<td>225</td>
<td>142</td>
<td>1068</td>
<td>492</td>
<td>158</td>
<td>215</td>
<td>191</td>
<td>57</td>
<td>449</td>
<td>2997</td>
<td>68,28%</td>
</tr>
<tr>
<td>Institutional Public (hospital)</td>
<td>93</td>
<td>54</td>
<td>82</td>
<td>101</td>
<td>39</td>
<td>39</td>
<td>54</td>
<td>43</td>
<td>134</td>
<td>639</td>
<td>14,55%</td>
</tr>
<tr>
<td>Institutional Private (hospital)</td>
<td>24</td>
<td>13</td>
<td>97</td>
<td>42</td>
<td>8</td>
<td>15</td>
<td>23</td>
<td>5</td>
<td>36</td>
<td>263</td>
<td>0,06%</td>
</tr>
<tr>
<td>Wholesale Pharmacy</td>
<td>21</td>
<td>7</td>
<td>130</td>
<td>21</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>35</td>
<td>228</td>
<td>0,05%</td>
</tr>
<tr>
<td>Consultant Pharmacy</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>12</td>
<td>0,003%</td>
</tr>
<tr>
<td>Manufacturing Pharmacy</td>
<td>8</td>
<td>1</td>
<td>198</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>8</td>
<td>0</td>
<td>26</td>
<td>250</td>
<td>0,06%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>371</td>
<td>217</td>
<td>1584</td>
<td>666</td>
<td>210</td>
<td>273</td>
<td>279</td>
<td>108</td>
<td>681</td>
<td>4389</td>
<td>100%</td>
</tr>
</tbody>
</table>

Source: obtainable from the SAPC website
Table 1.1 shows a list of pharmacy sectors contributing to access to pharmaceutical care for the public. All the sectors of pharmacy play a vital role in ensuring the availability of essential medicines and related remedies and services in the country.

The SAPC (2011) published the document “Pharmacy Human Resources in South Africa”, which demonstrated the distribution of pharmacies in South Africa as indicated in Table 1.2 below.

Table 1.2: Distribution of pharmacies per province – ratio of pharmacies per 100,000 members of the population (1st Column with all sectors, 2nd and 3rd column have Community and Institutional sectors respectively) in December, 2011

<table>
<thead>
<tr>
<th>Province</th>
<th>Population</th>
<th>Pharmacies</th>
<th>Pharmacies/ 100k</th>
<th>Pharmacies/ 100k</th>
<th>Pharmacies/ 100k</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC</td>
<td>6,648,600</td>
<td>324</td>
<td>4.87</td>
<td>2.83</td>
<td>1.67</td>
</tr>
<tr>
<td>FS</td>
<td>2,902,400</td>
<td>210</td>
<td>7.24</td>
<td>4.44</td>
<td>2.34</td>
</tr>
<tr>
<td>GP</td>
<td>10,531,300</td>
<td>1,723</td>
<td>16.36</td>
<td>11.18</td>
<td>1.63</td>
</tr>
<tr>
<td>KZN</td>
<td>10,449,300</td>
<td>622</td>
<td>5.95</td>
<td>4.23</td>
<td>1.29</td>
</tr>
<tr>
<td>LP</td>
<td>5,227,200</td>
<td>189</td>
<td>3.62</td>
<td>2.45</td>
<td>1.05</td>
</tr>
<tr>
<td>MP</td>
<td>3,606,800</td>
<td>208</td>
<td>5.77</td>
<td>4.24</td>
<td>1.41</td>
</tr>
<tr>
<td>NC</td>
<td>1,147,600</td>
<td>93</td>
<td>8.10</td>
<td>3.92</td>
<td>4.10</td>
</tr>
<tr>
<td>NW</td>
<td>3,450,400</td>
<td>223</td>
<td>6.46</td>
<td>4.03</td>
<td>2.29</td>
</tr>
<tr>
<td>WC</td>
<td>5,356,900</td>
<td>712</td>
<td>13.29</td>
<td>8.59</td>
<td>3.25</td>
</tr>
<tr>
<td>TOTAL</td>
<td>49,320,500</td>
<td>4,304</td>
<td>8.73</td>
<td>5.65</td>
<td>1.76</td>
</tr>
</tbody>
</table>

Source: Pharmacy Human Resources in South Africa (SAPC, 2011)

Gauteng Province (GP) and Western Cape (WC) which are more urban than other provinces in SA, had the highest number of pharmacies. GP population is similar to that of Kwa-Zulu Natal KZN but it had almost three times as many pharmacies as KZN. The pharmacy distribution in 2011 indicated a maldistribution and need for more pharmacies in the more rural provinces, e.g. Eastern Cape (EC), Limpopo (LP).

Table 1.3: Distribution of pharmacies per province in December, 2011 vs in November, 2014

<table>
<thead>
<tr>
<th>Year</th>
<th>EC</th>
<th>FS</th>
<th>GP</th>
<th>KZN</th>
<th>LP</th>
<th>MP</th>
<th>NW</th>
<th>NC</th>
<th>WC</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 2011</td>
<td>324</td>
<td>210</td>
<td>1723</td>
<td>622</td>
<td>189</td>
<td>208</td>
<td>223</td>
<td>93</td>
<td>712</td>
<td>4304</td>
</tr>
<tr>
<td>Total 2014</td>
<td>371</td>
<td>217</td>
<td>1584</td>
<td>666</td>
<td>210</td>
<td>273</td>
<td>279</td>
<td>108</td>
<td>681</td>
<td>4389</td>
</tr>
<tr>
<td>Difference</td>
<td>47 more</td>
<td>7 more</td>
<td>139 less</td>
<td>44 more</td>
<td>21 more</td>
<td>65 more</td>
<td>56 more</td>
<td>15 more</td>
<td>31 less</td>
<td>85 more</td>
</tr>
</tbody>
</table>
Chapter 1: Introduction

There were 139 and 31 decreases in the number of pharmacies in GP and WC respectively since 2011. The decrease was attributed to the SAPC project of pharmacy grading. In that project SAPC conducted monitoring inspections in 2013 and 2014 in all registered pharmacies. Those pharmacies that were closed without informing SAPC were identified and removed from the register. The rest of the provinces showed an increase, as indicated in Table 1.3, with the overall increase of 85 pharmacies since 2011. The other significant factor to consider for the low number of increase in registered pharmacies since 2011, is that applications for pharmacy relocation, and one for change of ownership require approval and follow the process of application for a license. These applications are discussed under 4.4.

1.2 BACKGROUND AND RATIONALE FOR THE STUDY

The NDoH receives the applications (See Appendix 1) and evaluates them according to specific criteria and requirements (See Appendix 2). A duplicate of the application form is directed to the SAPC for GPP evaluation. Desktop GPP evaluation forms the major part of the pharmacy premises licence approval process. If there are identified shortcomings during the GPP evaluation, the SAPC will inform the applicant via e-mail and the applicant will respond directly to the SAPC as part of the process. No application will be further considered for approval if it is not GPP-compliant. After the completion of the GPP evaluation, the SAPC recommends to the NDoH whether to approve the application or not. Based on the SAPC recommendations and the NDoH evaluation outcome, the Director-General (DG) (or the delegate) of the NDoH will or will not grant the pharmacy licence. There is an appeal process in place in the case of a dispute arising from the application outcome, either from the public or the applicant. The appeal process is specified in the Pharmacy Act, 1974 (Act No. 53 of 1974).

Five categories of pharmacies require a licence, namely: manufacturing, wholesale, institutional, consultant and community. The manufacturing and wholesale pharmacy licence applications require prior approval by the Medicines Control Council (MCC) for Good Manufacturing Practice (GMP) and Good Wholesale and Distribution Practice (GWDP) compliance respectively. The licence will only be issued if the application complies with all the relevant requirements. In addition to the above five categories, the applications are further classified as follows: new, relocation or change of ownership. Relocation and change of ownership applications may also include a change in trading title. Applications for only a change in trading title require a different approach and will therefore be excluded from the study.
The current licence approval criteria of the NDoH and the SAPC GPP are shown in Appendices 2 and 3 respectively. The NDoH’s criteria for approval include details of the prospective pharmacy site in relation to the number of existing pharmacies in the area and the size of the population in that area. In an urban area, only one pharmacy per 5,000 population (1:5,000) is permitted, except in the case of shopping malls, where siting is based on the number of footfalls. The NDoH’s criteria were based on the 2001 National Census statistics and not the National Census statistics of 2011. In February, 2014 the NDoH published revised criteria to approve pharmacy licences which refer to the latest available census information provided by Stats SA. These criteria do not apply to the target population of this study.

Since the process of pharmacy licence approval is governed by guidelines and standards, it aroused the curiosity of the researcher to determine whether its execution is favourable to the national health outcomes or not and whether the guidelines and SOPs available are appropriate to ensure that the health outcomes are realised. The researcher’s proposal topic was effected at the beginning of 2013 and hence selection of the 2012 data review, the most recent available.

The NDoH takes a minimum of three months to process and conclude a licence application for institutional, community and consultant pharmacies, and longer in the case of manufacturing and wholesale cases due to the need for GMP and GWDP compliance. Applications from the latter sectors can take a year or longer to process depending on the time taken by the MCC to conclude its processes, which are altogether separate. The pharmacy premises licence approval process is outlined in Table 1.4 below.
Table 1.4:  Approval process of pharmacy licence application

<table>
<thead>
<tr>
<th>Activities in licence approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Receipt of application by the NDoH</td>
</tr>
<tr>
<td>2. Arrangement for site inspection by the NDoH</td>
</tr>
<tr>
<td>3. Inspection is conducted by the NDoH</td>
</tr>
<tr>
<td>4. Complete application is sent to the SAPC</td>
</tr>
<tr>
<td>5. GPP evaluation is done by the SAPC, guidelines stipulate within 42 days</td>
</tr>
<tr>
<td>6. For Manufacturing or Wholesale sectors: GMP and GWDP evaluation is done by MCC</td>
</tr>
<tr>
<td>7. Evaluation of site inspection by the NDoH</td>
</tr>
<tr>
<td>8. GPP &amp; site compliance conclusion (including GMP/GWDP if applicable)</td>
</tr>
<tr>
<td>9. Licence recommendation/non-recommendation by the SAPC, outcome is sent to the NDoH</td>
</tr>
<tr>
<td>10. Licence approval/disapproval by the NDoH</td>
</tr>
<tr>
<td>11. Licence issue in case of approval by the NDoH</td>
</tr>
<tr>
<td>12. Recording of a licence by applicant with the SAPC within 30 days of approval</td>
</tr>
</tbody>
</table>

The GPP evaluation process is presented in Appendix 4. According to the SAPC, it takes 42 days to perform the GPP evaluation process in a licence application, if all the required information is submitted.

The fee levied for pharmacy licence applications is R1,000.00 which the NDoH and the SAPC share, R400.00 and R600.00 respectively. According to the SAPC’s 2013 process costing results, the GPP evaluation resources cost per application was R2,815.22 (See Appendix 5). The NDoH’s cost of resources was not documented. The process at the time of data collection was the same as that in 2012, indicating that the cost of resources used is greater than the fee levied.

Applicants also incur costs during the process of pharmacy premises approval. The common costs include leasing of premises, architect charges and potential recruitment and retention of personnel. If the service is ineffective, e.g. delays caused by the NDoH or the SAPC, some applications might lose valuable resources or investments. During a discussion with an applicant, who is a pharmacist and a sole proprietor, he mentioned incurring the following costs while the application was in process (in addition to the application fee).
Rent for leased premises: R 20,000.00 per month for three months;
Transport and travel: estimated at R 2,500.00;
Communication: estimated at R 1,000.00.

The costs listed above indicate that a delayed licencing process has cost implications for both parties.

In a study of a weakness determination and analysis model for business process improvement, Coskun et al (2008) stated that before a business process could be improved, an organisation should have a detailed and accurate picture of how it is currently working, including its strengths and weaknesses. Change and improvement are concepts which will remain within organisations, but because the conditions regarded as excellent in the past do not retain their status, with time they just become ordinary.

The process of GPP evaluation at the SAPC has not changed since 2012 but the approach to the evaluation was reviewed. Prior to 2013, only one unit (Practice) of the three units (Education, Practice and Registration) in the Professional Affairs Department was involved with the process. In 2013 all three units in Professional Affairs were included in GPP evaluation. Each of the three units had one officer, two practitioners, two managers and a senior manager (senior managers remain accountable to the overall unit primary functions). Each unit prioritises tasks that serve at their respective Committee of Council. In the study all the three units in Professional Affairs were included because there were applications from 2012 that were still under evaluation in 2013 and 2014. The three units now share their tasks which include but not limited to:

(a) Matters relating to pharmacy education and training: accreditation of providers and/or courses, secretariat, persons, pre-registration evaluations;
(b) Matters relating to pharmacy practice: approval of premises, GPP evaluations, tutors, responsible pharmacists, personnel;
(c) Matters relating to registration or deregistration: of persons and organisations (pharmacists, pharmacist interns, community service pharmacists, tutors, responsible pharmacists, personnel, premises); and
(d) Secretariat function to the committees of Council.

It is envisaged that the results of this study will provide valuable information, which could be used to strengthen the future pharmacy premises licence approval guidelines and process. No similar study has been found in the literature survey.
1.3 RESEARCH QUESTIONS

Are the NDoH and the SAPC adhering to the SOPs and guidelines when processing pharmacy premises licence applications and are these processes best in expediting access to pharmaceutical care in the country?

1.4 AIMS OF THE STUDY

- To describe the service for pharmacy premises licence approval during the period 01 January, 2012 to 31 December, 2012
- To determine the perceptions of the task and processes of involved staff (at the NDoH and the SAPC).

1.5 OBJECTIVES OF THE STUDY

The objectives of the study were to:
1. document and carry out a critical review of the steps involved in processing applications for pharmacy premises licences.
2. determine whether the approval process complies with the current SOPs and guidelines for pharmacy premises licence approval.
3. identify the factors which cause deviations from the SOPs and guidelines for pharmacy premises licence approval.
4. describe the perceptions of the task and processes of involved staff (at the NDoH and the SAPC).
5. identify whether the process of pharmacy premises licence approval ensures an optimal response to the country’s needs in terms of access to pharmaceutical care.

1.6 SIGNIFICANCE OF THE STUDY

The study has practical significance as access to pharmaceutical care still remains a challenge in South Africa. It is therefore worth investigating the process of pharmacy premises licence approvals to identify and address gaps within the service and to optimise access to pharmaceutical care in line with the national norms and standards.

1.7 OUTLINE OF THE DISSERTATION

Chapter 1 explains the background and rationale for the study, the problem statement, the research question, the aims and objectives and the significance of the study. Chapter 2
introduces the literature and previous studies that are relevant to this study. In Chapter 3 the
method used in this study is described in detail. The results and discussion thereof are
provided in Chapter 4. Chapter 5 includes a summary of the results, the conclusion and the
recommendations of the study.
CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

In this chapter, the literature review is presented, focusing on research studies and articles which are relevant to the subject of pharmacy premises approval. It also focuses on legislative requirements for such.

2.2 PROCESSES FOR THE REGISTRATION OF PHARMACY PREMISES

2.2.1 Australia

The Australian application process which relates specifically to the approval of the establishment of a new pharmacy or the relocation of an existing pharmacy is outlined in the Pharmacy Location Rules Applicant's Handbook of the Australian Department of Health and Ageing (Australian Department of Health and Ageing, 2011).

Section 90 of the Australian National Health Act, 1953, as stated in their pharmacy location rules, provides for the Secretary of the Department of Health and Ageing to approve a pharmacist's application to supply pharmaceutical benefits at particular premises. Pharmaceutical benefits are medicines or medicinal preparations for which the Commonwealth of Australia will pay. The Department of Health and Ageing provides a secretarial service to the Australian Community Pharmacy Authority (ACPA) which serves as the liaison with pharmacists. The duties of ACPA include:

- Referring applications for the ACPA's consideration;
- Seeking comments from pharmacists in the vicinity of a proposed pharmacy;
- Liaising with applicants on required documentation and application status;
- Providing guidance and assistance on the pharmacy location rules and the application process to any interested persons;
- Communicating ACPA recommendations to the Secretary.

Generally, the Secretary can only approve an application which has been recommended by the ACPA. The Secretary does not require a recommendation by the ACPA to approve applications for a change of pharmacy ownership or an expansion or contraction in the size
Chapter 2: Literature Review

of pharmacy premises. The function of the ACPA is to consider applications for the supply of pharmaceutical benefits at particular premises and to recommend to the Secretary whether the application be approved or not. In making its recommendations, the ACPA must comply with the rules determined by the Australian Minister of Health under section 99L of the Act (the pharmacy location rules).

2.2.2 The United States of America (USA): example Florida

According to the website of the Florida Board of Pharmacy in the USA, it is responsible for pharmacy licensure in the state. A pharmacy licence application is received and when deemed complete, the Board authorises an inspection. Upon successful completion of the inspection, the inspector notifies the Board office if the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 30 days. This process is applicable to community pharmacies (Florida Board of Pharmacy, 2013).

2.2.3 Ghana

According to the Ghana Pharmacy Council an application to operate a pharmacy is made to the Pharmacy Council office responsible for the area in which the applicant intends to operate. The applicant completes and submits the prescribed application forms, accompanied by the appropriate fee. A site inspection is carried out by officers of the regional offices of the Pharmacy Council after which a recommendation is made to the Council. The application is approved by the Pharmacy Council and is valid for a specified period of time (Ghana Pharmacy Council, 2014).

2.2.4 Kenya

The Pharmacy and Poisons Board of Kenya considers pharmacy premises licence applications. The application fee is 5,000 Kenya shillings. Upon receipt of the completed application forms and documents, the application is evaluated and the applicant is advised in writing whether the application was successful or not. In conducting the evaluation, the Board may arrange an interview for the applicant (superintendent) by the Practice Committee of the Board. If the interview is successful, an inspection of the proposed company’s premises will be conducted by a pharmaceutical inspector to assess the suitability of the intended business. On its website, the Pharmacy and Poisons Board of Kenya mentioned that having considered all factors and matters relating to the application the Board will either issue a certificate of registration of premises or in the case of an
unsuccessful application, advise the applicant in writing, clearly stating the reasons the application was unsuccessful.

In the case of an unsuccessful application, the applicant will be given further opportunity to revise and comply. Where the applicant is able to revise the application and comply with the requirements a licence will be issued. If otherwise the premises shall remain unregistered and the file will be closed after approximately six months from the date of initial application (Republic of Kenya Pharmacy and Poisons Board, 2014).

2.2.5 South Africa

In South Africa, pharmacy ownership is open to lay persons with conditions stipulated in the Regulations relating to their ownership and licencing in terms of Sections 22 and 22A of the Pharmacy Act, 1974 (Act No. 53 of 1974). At the first National Pharmacy Conference, hosted by the SAPC at Sun City on 23-26 June, 2013, the pharmacy profession recommended to the SAPC that lay ownership of pharmacies be reviewed. During discussions the profession mentioned that the arrangement did not serve the purpose it was intended for, i.e. to ensure availability of pharmacies in rural areas to address the serious health challenges of lack of equity and access to pharmaceutical care in these areas.

The researcher was given permission by the SAPC to view and refer to the report entitled: “Distribution of Community Pharmacies in the RSA” based on an unpublished thesis. In this report, the Medicine Usage in South Africa (MUSA) unit of the North-West University conducted a study in 2009 for the SAPC which provided basic information for an alternative system to “regulate and measure” community pharmacy distribution (in terms of pharmacy licences issued) at national, provincial, district and local levels (i.e. the four recognised governmental structures) (Medicine Usage in South Africa, 2009). In the report MUSA recommended compliance with the principles of the NDP, while properly addressing the needs of both patients and providers of pharmaceutical care. The report provided the SAPC with the number of community pharmacies (using the SAPC Register system data) per municipality over the period between 2003 and 2008. It highlighted that from the viewpoint of a provider the provision of a pharmaceutical service(s) must not only be “viable” (referring to a relatively short period) but must also be sustainable (i.e. relatively long periods). “Competition” must be limited to ensure that “over”-supply of providers in certain areas is controlled, whilst provision should be made to support the establishment of community pharmacies in areas where they are not available or are under-supplied. Some municipalities, particularly in urban areas, showed evidence of over-supply while some municipalities in rural areas were severely under-supplied.
Since pharmacy ownership is open to lay persons, this study also considers information about the ownership type and whether the time or effort taken in processing applications are similar regardless of the ownership type.

This study included the distribution (in numbers) of pharmacy applications per province, but not per municipality.

### 2.2.6 The Pharmaceutical Society of South Africa (Community Pharmacist Sector)

In February, 2014 the NDoH published new proposed criteria for the issuing of licences for pharmacy premises for implementation (NDoH, 2014). The NDoH did not consult with the SAPC when reviewing their pharmacy licensing criteria. In an article on the proposed new criteria for the issuing of licences for pharmacy premises, a concern was raised that there was uncertainty as to whether or not the NDoH followed the correct procedures (in terms of the Pharmacy Act 53 of 1974) (SAPC, Pharmacy Act 53 of 1974) and requirements when amending the regulations (i.e. consultation with the SAPC or Executive Committee of the Council regarding the proposed pharmacy licence criteria) (Du Toit, 2014). The author of the article represented the Community Pharmacist Sector of the Pharmaceutical Society of South Africa (PSSA) and is also a Council member at the SAPC.

In terms of GPP compliance, they raised a concern that initial non-compliance would mean automatic rejection of the application by the NDoH and that the applicant would have to submit a new application, which would most probably include payment of the fees again. They raised a concern that if new premises were not operational in the shortest possible time, GPP evaluation of, among others, floor and site plans, must be transparent and consistent to support the economic viability of the new pharmacy premises.

### 2.2.7 Staff perceptions

Arnetz (1999), in the study “Staff Perception of the Impact of Healthcare Transformation on Quality of Care”, recommended that staff perceptions be used as an additional indicator of quality of care. The study mentioned that to improve quality of care management should encourage staff involvement in everyday management issues, which included up-to-date information about organisational goals and mission. It is also envisaged that staff perceptions will provide information regarding, but not limited to, each person’s own belief regarding their capability and commitment, colleagues and the organisation in performing the task. These perceptions are likely to affect the task effort and the level of difficulty of goals selected for performance evaluation.
2.2.8 Management principles

The Chartered Quality Institute (2013) considers total quality management (TQM) as an appropriate management approach to an organisation’s long-term success through customer satisfaction. In a TQM effort, all members of an organisation should participate in improving processes, products, services and the culture in which they work, i.e. customer-focus; total employee involvement; process-centred; integrated system; strategic and systematic approach; continual improvement; fact-based decision-making; and communication.

2.3 SUMMARY

Chapter 2 detailed the literature reviewed in this study. There was a lack of information and evidence on this topic.
CHAPTER 3

METHOD

3.1 INTRODUCTION

This chapter presents information about the research study design, sampling, study sites, study period and the pilot study. The chapter also explains the data collection instruments, data entry and analysis, bias, reliability, validity and the issues concerning ethical consideration.

This chapter justifies and describes the procedures followed to answer the research question.

3.2 STUDY DESIGN

An investigational study was carried out in terms of the principles cited by Donabedian, i.e. structure, process and outcomes (Donabedian, 2005). The study design was cross-sectional, descriptive and quantitative. Data were collected with a retrospective record review and a self-administered questionnaire and were captured and manually categorised.

3.3 STUDY SITE

The study was conducted at the NDoH and the SAPC offices in Pretoria, South Africa.

3.4 STUDY PERIOD

Data collection for applications submitted over the period January to December, 2012 occurred during April, 2014 to August, 2014, after approval was granted by the MREC (See Appendix 12) and both the NDoH and the SAPC (See Appendices 7a and 7b).

3.5 STUDY POPULATION

3.5.1 Inclusion criteria

The study population included all pharmacy premises licence applications received during the period 01 January, 2012 to 31 December, 2012 with respect to the sectors (manufacturing, wholesale, institutional, consultant or community) and classification (new,
relocation, change of ownership, relocation and trading title or change of ownership and trading title). The number of applications was initially estimated at approximately 250. The actual count was 404, of which 325 could be evaluated.

All staff working with 2012 pharmacy premises licence approval at both the NDoH and the SAPC, and who had received the respondent information leaflet (See Appendix 8) and who signed consent statements (See Appendix 9), were included in the study (20 participated). Accordingly no sample selection was done for this group of respondents either. Fourteen respondents from the SAPC and six from the NDoH took part. The seventh potential NDoH respondent was willing to participate, but was not available during the period of data collection.

3.5.2 Exclusion criteria

The study excluded applications that were concluded and rejected at the NDoH without being referred to the SAPC. Data, where dates were earlier than the application received date, were also removed from the sample to uphold validity. Data that were found at the SAPC, but not recorded at the NDoH, were also excluded.

3.6 DATA COLLECTION INSTRUMENTS

All data were collected by the researcher. They were collected in two ways.

3.6.1 Retrospective record review

The records of the 2012 pharmacy premises licence applications were used to determine the duration of the steps in pharmacy premises licence approval initiated in 2012. Data were collected at the NDoH and the SAPC independently. The data sets were compared, matched and reconciled to verify that all applications received during the period 01 January, 2012 to 31 December, 2012, other than those indicated in the exclusion criteria, were included (See Appendix 10).

3.6.2 Self-administered structured questionnaire

A self-administered structured questionnaire (See Appendix 11) was used to collect information about the perceptions of staff regarding the task in relation to the provision of effective and efficient pharmaceutical services by the applicants to the South African public. The questionnaire consisted of a set of questions which addressed the variables of processing pharmacy premises licence applications. The researcher explained the purpose
of the study in a meeting with respondents at their respective places of employment. The questionnaires were administered by the researcher to the study group. Respondents were requested to complete the questionnaire without any discussion with colleagues. Consent forms and completed questionnaires were kept safely. All information was treated confidentially and all identities remained anonymous.

3.7 PILOT STUDY

A pilot study was conducted on both the data review sheets using the first 10 of 2012 pharmacy licence applications and the questionnaires with five volunteer Customer Care Officers at the SAPC. The 10 applications were also included in the actual study. However the five respondents were not part of the actual study. The pilot study tested the reliability and validity of the questionnaire and record review sheets.

Results obtained from the pilot study were used to check the feasibility of the study. This assisted the researcher in improving the quality of the tools (to ensure that they achieved the appropriate answer to the research question) and offered an opportunity to apply the process, thereby minimising bias. Necessary changes were made to the data collection tools prior to effecting the actual data collection.

3.8 DATA ENTRY AND ANALYSIS

Data were captured by the researcher on a Microsoft Excel™ spread sheet. All data entered were checked for accuracy and completeness repetitively. Data were also cross-checked for accuracy and completeness in SAS, Release 9.2, running on Microsoft Windows Vista MIS. Data analysis took place in consultation with a statistician. Data were analysed with suitable descriptive statistical analysis. Categorical variables were summarised by frequency counts and percentages. Statistical procedures were performed using Microsoft Excel™, SAS, Release 9.2, running on Microsoft Windows Vista. All results were presented in either frequency Tables or Figures, followed by a brief discussion.

3.9 RELIABILITY AND VALIDITY

The use of multiple methods of data collection, such as interviews, observation and document analysis leads to trustworthiness (Maree, 2007). Data were obtained from different MIS sources used for this task, namely the SAPC Register MIS, the SAPC Dashboard MIS and the NDoH MIS. The researcher requested 2012 pharmacy premises licence applications
data which were provided by different Information Technology (IT) specialists from the three different MIS.

The data were collected over a period of 16 weeks, with each relevant unit of the NDoH and the SAPC being contacted to clarify data correctness when the need arose. Five consultations with the statistician and regular meetings with supervisors regarding the interpretation of the data enhanced their trustworthiness. Questionnaires were used to strengthen data reliability. Data triangulation was used (the use of questionnaires and database records) as referred to by Brink et al (2012). All data entered were cross-checked for accuracy and correctness. Validity was also strengthened through the conducting of the pilot study. Data from fields that were not evaluable (e.g. where no dates had been entered in some fields but the application had been finalised, where processing dates were earlier than the application received date) were removed to uphold validity. Discrepancies were identified and rectified prior to the data analysis.

3.10 ETHICAL CONSIDERATIONS

Ethical clearance for the study was obtained from the MREC at the University of Limpopo. The NDoH and the SAPC granted permission to conduct the study. On the 2012 data review, the names and identification codes of the applications and those of staff (on step analysis) were removed and replaced with numbers. The aims and objectives of the study were clearly explained to the respondents and written informed consent was obtained prior to administering the data collection instruments (DCIs) (See Appendices 8 and 9). Participants were informed that their participation was voluntary and that they could withdraw from the study at any time, should they wish to do so. All information was treated confidentially and all identities remained anonymous.

3.11 SUMMARY

Chapter 3 detailed the methodology followed in this study. The results of the data collected over the 16-week study period will be presented in Chapter 4.
CHAPTER 4
RESULTS AND DISCUSSION

4.1 INTRODUCTION

In this chapter results of the statistical analysis are presented in tables, figures and short descriptions of the indicators. Al-Mashari et al (2001) stated that increases in consumer requirements for both product and service efficiency and effectiveness resulted in business process reengineering (BPR). Macintosh (2003) described reengineering as the radical redesign of business processes to achieve dramatic improvements in critical, contemporary measures of performance, such as cost, quality, service, and speed. The researcher in this chapter aimed to address the objectives of the study which were:

1. to document and carry out a critical review of the steps involved in processing applications for pharmacy premises licences;

2. to determine whether the application process complied with the current SOPs and guidelines for pharmacy premises licence approval;

3. to identify the factors which caused deviations from the SOPs and guidelines for pharmacy premises licence approval;

4. to describe the perceptions of the task and processes of involved staff (at the NDoH and the SAPC); and

5. to identify whether the process of pharmacy premises licence approval ensures an optimal response to the country’s needs in terms of access to pharmaceutical care.

The results were expressed as Tables and Figures. Data were characterised and entered on a spreadsheet with information required for analysis as shown in Table 4.1 below.
### Table 4.1: Example of the spreadsheet of data extracted with eight of the 325 evaluated applications (2012)

<table>
<thead>
<tr>
<th>No.</th>
<th>Date received</th>
<th>Date sent to SAPC</th>
<th>SAPC start date</th>
<th>SAPC end date</th>
<th>NDoH Meeting date &amp; outcome</th>
<th>Ownership type</th>
<th>Category</th>
<th>Application type</th>
<th>Province</th>
<th>Date approved</th>
<th>Application status</th>
</tr>
</thead>
<tbody>
<tr>
<td>108</td>
<td>28-May-12</td>
<td>08-Jun-12</td>
<td>18-Jun-12</td>
<td>29-Jul-13</td>
<td>08-Mar-13</td>
<td>Sole Proprietor</td>
<td>Community</td>
<td>New Application</td>
<td>Western Cape</td>
<td></td>
<td>Negative GPP</td>
</tr>
<tr>
<td>109</td>
<td>21-Aug-12</td>
<td>07-Sep-12</td>
<td>19-Sep-12</td>
<td>04-Oct-12</td>
<td>+ve</td>
<td>Company</td>
<td>Wholesaler</td>
<td>New Application</td>
<td>Eastern Cape</td>
<td>09-Dec-13</td>
<td>Finalised</td>
</tr>
<tr>
<td>111</td>
<td>24-Jul-12</td>
<td>07-Sep-12</td>
<td>19-Sep-12</td>
<td>20-Nov-12</td>
<td>+ve</td>
<td>Sole Proprietor</td>
<td>Community</td>
<td>Relocation</td>
<td>Kwa-Zulu-Natal</td>
<td>31-Jan-14</td>
<td>Finalised</td>
</tr>
<tr>
<td>113</td>
<td>09-Apr-12</td>
<td>20-Apr-12</td>
<td>25-Apr-12</td>
<td>13-Sep-12</td>
<td>+ve</td>
<td>Close Corporation</td>
<td>Community</td>
<td>Change of Ownership</td>
<td>Gauteng</td>
<td>08-Oct-12</td>
<td>Finalised</td>
</tr>
<tr>
<td>114</td>
<td>23-Apr-12</td>
<td>26-Apr-12</td>
<td>08-May-12</td>
<td>05-Sep-12</td>
<td>08-Mar-13</td>
<td>Company</td>
<td>Community</td>
<td>New Application</td>
<td>Gauteng</td>
<td>14-Jun-13</td>
<td>Finalised</td>
</tr>
<tr>
<td>115</td>
<td>31-Jul-12</td>
<td>08-Sep-12</td>
<td>18-Sep-12</td>
<td>01-Mar-13</td>
<td>04-Oct-12</td>
<td>Company</td>
<td>Private Institution</td>
<td>Change of Ownership</td>
<td>Mpumalanga</td>
<td>15-May-13</td>
<td>Finalised</td>
</tr>
<tr>
<td>116</td>
<td>31-Jul-12</td>
<td>07-Sep-12</td>
<td>19-Sep-12</td>
<td>11-Mar-14</td>
<td>+ve</td>
<td>Company</td>
<td>Manufacturer</td>
<td>Relocation</td>
<td>Gauteng</td>
<td>26-May-14</td>
<td>Finalised</td>
</tr>
<tr>
<td>117</td>
<td>08-Mar-12</td>
<td>08-Mar-12</td>
<td>29-Mar-12</td>
<td>02-Jul-12</td>
<td>+ve</td>
<td>Close Corporation</td>
<td>Community</td>
<td>Change of Ownership</td>
<td>Western Cape</td>
<td>03-Aug-12</td>
<td>Finalised</td>
</tr>
</tbody>
</table>

Key: +ve = Licensing Committee gave positive response for approval (subject to other processes' outcome).

Note: The dates in this table represent accurate information. Where the date of a NDOH meeting precedes SAPC dates it is because the application has been given approval conditional to a satisfactory GPP report.
The study excluded applications that were concluded at the NDoH without the SAPC GPP evaluation, had invalid dates (where processing dates were earlier than the application received date) or had no dates captured in relevant fields but were finalised. After data cleaning 325 applications could be evaluated. The 79 of the 404 applications that were not evaluable and subsequently excluded were from the NDoH. The challenges with most of the 79 applications included dates that were not captured correctly (e.g. end dates being earlier than start dates, GPP receipt dates being earlier than sent dates, GPP having date records but not the NDoH and some with duplication).

The SAPC has a commendable MIS in place resulting in their data being easily retrieved, evaluated and cross-checked. The NDoH’s data capturing system had challenges and the staff acknowledged this to the researcher. Table 4.2 shows 325 applications which were evaluated with only 187 (57.5%) being finalised. The remaining 138 (42.5%) did not have records of finalised dates (some reasons were awaiting GPP or MCC outcome) or data were not captured by the SAPC/the NDoH. At the SAPC, there were only 21 applications awaiting GPP finalisation with the rest finalised (93.5%) as shown in Table 4.2. Although there were applications from 2012 that appeared not to be finalised at data collection, it could not automatically be assumed that those 138 (42%) were not finalised. To some extent it could be attributed to the manufacturing and wholesale applications that were awaiting GMP inspection outcome. However human error during manual data capturing at the NDoH may have been the factor affecting the data integrity as well, especially considering that 42.5% of the 2012 outstanding applications were still to be finalised in 2014.

A summary of the number of applications processed from receiving (NDoH), the number of applications sent to the SAPC (GPP) and the number of applications finalised (at the SAPC and at the NDoH) was obtained using the spreadsheet in Table 4.1, and is presented in Table 4.2 below.

**Table 4.2: 2012 pharmacy licence applications path summary**

<table>
<thead>
<tr>
<th>Actual data at NDoH &amp; SAPC</th>
<th>Manual recorded NDoH sent to SAPC vs actual</th>
<th>Manual recorded received by SAPC vs actual receipt</th>
<th>Completed by SAPC</th>
<th>Finalised at NDoH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluable/valid</td>
<td>325</td>
<td>315</td>
<td>304</td>
<td>283</td>
</tr>
<tr>
<td>%</td>
<td>100%</td>
<td>96.9% of 325</td>
<td>93.6% of 325</td>
<td>87% of 325</td>
</tr>
</tbody>
</table>

One hundred and eighty seven (57.5%) of evaluated applications were finalised with the minimum and the maximum days taken being 44 and 760 respectively (See Table 4.3).
Table 4.3: Descriptive statistics showing summary of days spent on evaluation (SAPC)

<table>
<thead>
<tr>
<th>Applications</th>
<th>No</th>
<th>Complete (%)</th>
<th>Incomplete (%)</th>
<th>Minimum days</th>
<th>Maximum days</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAPC Start to SAPC End (GPP process)</td>
<td>325</td>
<td>93.50%</td>
<td>6.50%</td>
<td>6.00</td>
<td>677.00</td>
<td>252.26</td>
<td>159.02503</td>
</tr>
<tr>
<td>Received date to approval date (Whole process )</td>
<td>325</td>
<td>57.50%</td>
<td>42.50%</td>
<td>44.00</td>
<td>760.00</td>
<td>307.44</td>
<td>151.67378</td>
</tr>
</tbody>
</table>

The study assessed the number and records of applications, whether they matched at both the NDoH and the SAPC, what the requirements were and if processing of applications complied with requirements, e.g. timespan targets and whether applications were assessed similarly irrespective of the province, ownership, application type and type of sector. To achieve this objective they were analysed and reported by province, ownership, application type and type of sector.

Fiftyeight percent of evaluated applications were finalised at the NDoH by June, 2014 when data were collected. At the SAPC 93.5% of GPP evaluations for 2012 applications were complete at the time of data collection.

4.2 RESULTS AND DISCUSSION OF APPLICATIONS PER PROVINCE

The application breakdown per province, showing averages of minimum/maximum and the mean for days spent to process an application are shown in Table 4.4 below and Figure 4.1. The average time spent of 252 days in GPP evaluation was much longer than the 42 days stated in the SAPC SOP. It took an average of 316 days to finalise an application, including the issue of the licence by the NDoH. Only finalised applications were used to derive information listed in Table 4.4 and in Figure 4.1. The distribution of 2012 applications by province shows the highest number coming from GP at 42%. Although GP had the highest number of applications, since 2011 GP had a reduction of 139 pharmacies, the WC had a reduction of 31 pharmacies and the rest of the provinces had a slight increase (See Table 1.3.)

There were still fewer applications for pharmacy licences for the rural areas (villages and townships) compared to those for urban areas (towns, suburbs and cities). In the evaluated data only seven percent of applications were from rural areas. The increase in number of
Chapter 4: Results and Discussion

pharmacies since 2011 was only 85 as shown in Table 1.3. There should be general concern regarding the slow improvement in access to pharmaceutical care.
Table 4.4: Breakdown of 325 applications per province and the average time taken to process with minimum and maximum days of processing at both the NDoH and the SAPC

<table>
<thead>
<tr>
<th>Province</th>
<th>Quantity</th>
<th>Percent (%)</th>
<th>Number finalised</th>
<th>Days spent from receiving by NDoH to the SAPC completion (if completed)</th>
<th>Days spent at the SAPC for GPP evaluation (if completed)</th>
<th>Days spent from received to finalisation (whole process)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Days spent from receiving by NDoH to the SAPC completion (if completed)</td>
<td>2. Days spent at the SAPC for GPP evaluation (if completed)</td>
<td>3. Days spent from received to finalisation (whole process)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Min</td>
<td>Max</td>
<td>Mean</td>
</tr>
<tr>
<td>EC</td>
<td>20</td>
<td>6.2</td>
<td>11</td>
<td>189</td>
<td>551</td>
<td>315.0</td>
</tr>
<tr>
<td>FS</td>
<td>7</td>
<td>2.2</td>
<td>4</td>
<td>148</td>
<td>281</td>
<td>216.8</td>
</tr>
<tr>
<td>GP</td>
<td>136</td>
<td>41.8</td>
<td>80</td>
<td>48</td>
<td>786</td>
<td>287.8</td>
</tr>
<tr>
<td>KZN</td>
<td>57</td>
<td>17.5</td>
<td>32</td>
<td>28</td>
<td>688</td>
<td>291.4</td>
</tr>
<tr>
<td>LP</td>
<td>23</td>
<td>7.1</td>
<td>12</td>
<td>78</td>
<td>454</td>
<td>259.1</td>
</tr>
<tr>
<td>MP</td>
<td>19</td>
<td>5.8</td>
<td>15</td>
<td>92</td>
<td>594</td>
<td>283.4</td>
</tr>
<tr>
<td>NW</td>
<td>24</td>
<td>7.4</td>
<td>16</td>
<td>115</td>
<td>640</td>
<td>303.0</td>
</tr>
<tr>
<td>NC</td>
<td>4</td>
<td>1.2</td>
<td>3</td>
<td>214</td>
<td>549</td>
<td>318.3</td>
</tr>
<tr>
<td>WC</td>
<td>35</td>
<td>10.8</td>
<td>14</td>
<td>87</td>
<td>698</td>
<td>339.1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>325</td>
<td>100.00</td>
<td>187/325 =57.5%</td>
<td>Average/ province = 277</td>
<td>Average/ province = 252.3</td>
<td>Average/ province = 316.4</td>
</tr>
</tbody>
</table>
Figure 4.1: Average days taken to process an application per province at both the NDoH and the SAPC (only finalised applications were used to derive information)
Table 4.4 shows that the average time spent of 252.3 days was much longer than the 42 days stated in the SAPC SOP. Only complete applications were used to derive the information listed. It took an average of 316 days to finalise an application. There is a narrow margin between GPP completion and application finalisation, indicating that GPP delays the whole application, so that the whole process does not comply with guidelines. The average number of days spent from receipt by the NDoH to the SAPC completion was 277 and the average number of days spent at the SAPC for GPP evaluation was 252.3. The difference was 24.7 days, which was the average number of days an application spent at the NDoH prior to submission for GPP evaluation at the SAPC.

Applications assessed indicated that the NDoH’s and the SAPC’s evaluations by province did not expedite applications that came from provinces that needed more access, EC, KZN NW and NC. Although there are no specific data on distribution by province for rural versus urban areas, it is clear that there is a predominance of pharmaceutical activities in urban areas compared to the rural areas (see Table 1.3). The current NDoH criteria seem to encourage the situation in urban areas as they exclude the distance restriction in shopping malls. Most shopping malls are situated in urban areas.

SA Real Estate Investor magazine of Real Media, mentioned “Research shows that South African Shopping centre development trends are moving towards an oversupply situation in urban areas, yet retailers are still cautious when it comes to considering the opportunities within township and rural areas”. It further states that in SA, people living in rural areas and townships (or second economy locations) spend more than R 308 billion annually, representing 41 percent of total consumer spending. This implies that demand for services in rural areas could be greater than the current supply.

4.3 RESULTS AND DISCUSSION OF APPLICATIONS BY OWNERSHIP TYPE

Table 4.5 shows that 266 applications (81.9%) were from Companies (Co) and Close Corporations (CC) with only 15% being Sole Proprietor and Partnership applications. There has been a significant increase in the number of Co. and CC applications since pharmacy ownership was open to lay persons but there is no significant increase in the applications for rural areas by this group.

The researcher used physical addresses of applications to check the number of applications for rural against urban areas. There were 24 (7%) for rural and 301(93%) for urban. Of the 24, 15 applicants were Sole Proprietorship. Rural areas were not priority targets for applicants for Co. and CC pharmacies. Since there are more Co and CC applications overall
the NDoH and the SAPC need to do advocacy for the rural areas. One of the reasons for opening pharmacy ownership to lay persons was to have a fair distribution of pharmacies in South Africa (SA) and have more pharmacies in rural areas. This objective has not been achieved.

Applications assessed indicated that the NDoH and the SAPC evaluated ownership type similarly and without prejudice. Only finalised applications were used to derive information listed in Figure 4.3 below. Although the Partnership, Trust and Public Institutional categories took longer to process on average, they were few in number as shown in Table 4.5 when compared to the other types, thus making it difficult to infer that there was inequity in processing of applications.

**Table 4.5: Number of applications processed by ownership type**

<table>
<thead>
<tr>
<th>Ownership type</th>
<th>No of applications</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Close Corporation</td>
<td>113</td>
<td>34.8</td>
</tr>
<tr>
<td>Company</td>
<td>153</td>
<td>47.1</td>
</tr>
<tr>
<td>Partnership</td>
<td>4</td>
<td>1.2</td>
</tr>
<tr>
<td>Sole Proprietor</td>
<td>45</td>
<td>13.8</td>
</tr>
<tr>
<td>Public Institutional</td>
<td>8</td>
<td>2.5</td>
</tr>
<tr>
<td>Trust</td>
<td>2</td>
<td>0.006</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>325</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Figure 4.2: Average days taken to process an application by type of ownership at both the NDoH and the SAPC (only finalised applications were used to derive information)**
Chapter 4: Results and Discussion

4.4 RESULTS AND DISCUSSION OF APPLICATIONS BY APPLICATION TYPE

Application type is the applicant’s preference, as they can buy an existing pharmacy and choose “type” as new application type, i.e. three types of applications shown in Table 4.6 out of the five possible as mentioned in the introduction. The type ‘change of ownership’ took a shorter period of time to process than a new or relocation type of application because the premises were already licenced, the only change being that of ownership. However application requirements were similar to that of the other types. Applications assessed indicated that the NDoH and the SAPC evaluated application types similarly and without prejudice.

Table 4.6: Number of application processed by type (new, relocation, change in ownership at both the NDoH and the SAPC)

<table>
<thead>
<tr>
<th>Type of application</th>
<th>Number of applications</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Application</td>
<td>185</td>
<td>57%</td>
</tr>
<tr>
<td>Change of Ownership</td>
<td>77</td>
<td>24%</td>
</tr>
<tr>
<td>Relocation</td>
<td>63</td>
<td>19%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>325</td>
<td>100%</td>
</tr>
</tbody>
</table>

Figure 4.3: Average days taken to process an application by application type at both the NDoH and the SAPC (only finalised applications were used to derive information)
Chapter 4: Results and Discussion

One hundred and forty of the 325 applications (43%) evaluated were for relocation (77) and change of ownership (63); and those are already existing pharmacies. These do not increase the number of pharmacies despite an increase in the number of applications and provided clarity as to why the increase in the number of pharmacies is low.

To some extent they also explain that although the number of pharmacy applications for manufacturing and wholesale looks high (48), 20 of these applications were only for relocation and change of ownership.

4.5 RESULTS AND DISCUSSION OF APPLICATIONS BY PHARMACY SECTOR

Table 4.7 and Figure 4.4 show the data for sector and the average time spent in GPP evaluation by sector.

Table 4.7: Number of applications by pharmacy sector at both the NDoH and the SAPC

<table>
<thead>
<tr>
<th>Sector</th>
<th>No of applications</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community</td>
<td>259</td>
<td>79.7</td>
</tr>
<tr>
<td>Consultant</td>
<td>2</td>
<td>0.6</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>27</td>
<td>8.3</td>
</tr>
<tr>
<td>Private Institution (hospital)</td>
<td>7</td>
<td>2.2</td>
</tr>
<tr>
<td>Public Institution (hospital)</td>
<td>9</td>
<td>2.8</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>21</td>
<td>6.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>325</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

![Average days spent DOE to SAPC Evaluation.png](attachment:Average_days_spent_DOE_to_SAPC_Evaluation.png)
The GPP evaluation process for the manufacturing, wholesale and public institutional sectors took longer (above 300 average number of days) than private Institutional and Community sectors. The NDoH process/outcome depended on the MCC to finalise the manufacturing and wholesale sectors. Applications finalised for these two sectors together were 48 and 14 (29%) of those were finalised but 34 (71%) of those were not finalised which were not included in determining the average number of days spent. Therefore in total the number of applications for manufacturing and wholesale that were included in the data were 14 of the 138 finalised applications. These applications constitute 10% of the finalised data.

According to staff perceptions these two sectors seemed more complex to evaluate than the others. Staff also mentioned that the current guidelines/criteria and SOPs were not explicit on how each sector should be evaluated, resulting in subjectivity of and hence elapsed time differences for evaluations.

Data for applications from wholesalers and manufacturers are included as they play a role in providing access to pharmaceutical care through their vital part in ensuring availability of medicines and related substances in the country.

The public mostly use Community (almost 80% of applications) and Institutional/Hospital (5% public and private facilities combined) sectors for direct access to pharmaceutical care. As mentioned in the introduction three units at the SAPC carry out GPP evaluation, which process carries a high risk (with relatively high likelihood and impact) of applications not being processed on a first come/first serve basis. There is no integration of effort and sequence among evaluators. Each evaluator carried out the task when s/he chose. This approach may lead to situations such as unfair decisions, e.g. where two applicants targeted the same/similar area, one applied earlier and the other later. The later one may be approved before the earlier applicant leading to the disapproval of the earlier application due to proximity.

4.6 RESULTS AND DISCUSSION OF GPP EVALUATION HANDLING PER STEP

Process of pharmacy licence applications

1. **NDoH process**

This process is done manually.
2. GPP evaluation process

The GPP evaluation process of seven steps (outlined in Table 4.8) targeted 42 days to finalise and provide outcomes to the NDoH. It was estimated that each step would take approximately six days, taking resubmissions into account, with the expectation that applicants responded within 21 days after they received a letter explaining any shortcomings. If no response received within 21 days, a follow-up shortcoming letter is sent to the applicant, who must reply satisfactorily within another 21 days. If the applicant fails to respond satisfactorily, the application must be finalised with a refusal. That outcome must then be sent to the NDoH.

Considering that each person involved in the process was estimated to need an average of six days to process an application on their step, this study reviewed the data by time spent per step. Those steps which took less than or equal to 10 days were regarded as compliant according to SOP timelines (advised by the Statistician). Steps that took more than 10 days were regarded as non-compliant.
Table 4.8: GPP evaluation process step analysis at the SAPC

<table>
<thead>
<tr>
<th>PERSON AT SAPC with name of their step</th>
<th>Finance clerk (invoice payment)</th>
<th>Finance manager (release allocation)</th>
<th>Customer care Officer (process received docs from NDoH)</th>
<th>PA Officer (arrange inspection / report if required)</th>
<th>Practitioner (evaluate application)</th>
<th>Manager (approve application)</th>
<th>Senior manager (final verification)</th>
<th>Logistics clerk (finalise certificate and mail)</th>
<th>Total number of times handled by all</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of times handled in days &amp; its %</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>0-10 days spent is compliance</td>
<td>682</td>
<td>99%</td>
<td>317</td>
<td>69%</td>
<td>415</td>
<td>47%</td>
<td>76</td>
<td>68%</td>
<td>1465</td>
</tr>
<tr>
<td>&gt;10 days spent is non-compliance</td>
<td>5</td>
<td>1%</td>
<td>144</td>
<td>31%</td>
<td>462</td>
<td>53%</td>
<td>35</td>
<td>32%</td>
<td>852</td>
</tr>
<tr>
<td>Total No. of times handled in days &amp; its %</td>
<td>687</td>
<td>100%</td>
<td>461</td>
<td>100%</td>
<td>877</td>
<td>100%</td>
<td>111</td>
<td>100%</td>
<td>2317</td>
</tr>
</tbody>
</table>

Breakdown of non-compliance using handling time (in days) taken at a step

<table>
<thead>
<tr>
<th>Breakdown of non-compliance using handling time (in days) taken at a step</th>
<th>11-45</th>
<th>46-90</th>
<th>91-150</th>
<th>151-200</th>
<th>&gt; 200</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>96</td>
<td>48</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>144</td>
</tr>
<tr>
<td>378</td>
<td>12</td>
<td>18</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>462</td>
</tr>
<tr>
<td>17</td>
<td>12</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>35</td>
</tr>
<tr>
<td>648</td>
<td>173</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>852</td>
</tr>
<tr>
<td>783</td>
<td>178</td>
<td>55</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1052</td>
</tr>
<tr>
<td>97</td>
<td>33</td>
<td>10</td>
<td>3</td>
<td>3</td>
<td>145</td>
<td>145</td>
</tr>
<tr>
<td>162</td>
<td>29</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>195</td>
<td>195</td>
</tr>
<tr>
<td>2186</td>
<td>539</td>
<td>113</td>
<td>34</td>
<td>18</td>
<td>2890</td>
<td>2890</td>
</tr>
</tbody>
</table>

CORE OF GPP EVALUATION
Figure 4.5 below highlights the key areas of Table 4.8 and shows the GPP evaluation percentage split of compliance vs. non-compliance with SOP timelines, i.e. 10 days or less on a step to comply and more than 10 days to be non-compliant (irrespective of how many resubmissions were made). Bear in mind that the total number of applications was 325, to put the occasions and the time taken for processing into perspective.

In terms of the process more applications are handled at practitioner and manager level as they are the core evaluators, with the manager complying only in 484/1,536 applications. The handling of applications (1,536 times by a manager and 2,317 times by a practitioner) strongly suggests that a significant number of applications had more than two resubmissions. Practitioners, managers and senior managers are the main evaluators as indicated in Figure 4.5. The senior managers handled the fewest applications as they only carried out the final verification on recommendation or refusal.

Figure 4.5: Percentage of compliance vs. non-compliance to SOP timelines using the time spent for each step at the SAPC (number of resubmissions is not reflected)

The Customer Care Officers (47%) and Managers (32%) had below 50% compliance levels in terms of the duration of handling time spent on their step. These two steps are rate limiting and attention to them is required to address non-compliance. The other staff showed a compliance level of above 60% in handling time on a step. This excluded the number of resubmissions/ number of evaluation cycles.

Since the SOPs for applications accommodate the initial submission and two subsequent resubmissions, it means that the evaluation must have three cycles of evaluation by each person at the most. The GPP evaluation process is mainly done (core of evaluation) at the practitioner and manager levels with the senior manager only verifying the outcome (i.e.
handling the applications for a decision as per SOP). Responses to shortcomings and follow-up are handled by the practitioner and subsequently by the manager. Therefore the practitioner and manager handled application cycles more than other staff. Table 4.9 below shows the number of cycles the practitioner and manager evaluated per application.

Table 4.9: Number of cycles evaluated by main evaluators: practitioner and manager

<table>
<thead>
<tr>
<th>Number of evaluation cycles</th>
<th>Number of applications Practitioner evaluated</th>
<th>% of applications</th>
<th>Number of applications Manager evaluated</th>
<th>% of applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three or less</td>
<td>Comply</td>
<td>126</td>
<td>38,8%</td>
<td>189</td>
</tr>
<tr>
<td>Four times or more</td>
<td>Does not comply</td>
<td>199</td>
<td>61,2%</td>
<td>136</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>325</td>
<td>100%</td>
<td>325</td>
</tr>
</tbody>
</table>

Sixty-one percent of applications evaluated by the practitioners and 42% of applications evaluated by the managers do not comply with the SOP for the number of cycles permitted, another deviation from the SOP.

Table 4.3 previously showed that the SAPC had data for applications. From the 325 applications evaluated at the SAPC, 292 were evaluated with at least two submissions, which cited the site/floor plans as not complying with criteria. Site/floor plans were the major cause for resubmissions.

4.7 APPLICATION PROCESS: COMPLIES, PARTIALLY COMPLIES OR DOES NOT COMPLY WITH THE STANDARD BASED ON THE HOLISTIC DATA REVIEW RESULTS

According to both the NDoH and the SAPC, processes 1-8 in Table 4.10 below are envisaged to take an average of three months to finalise, as stated in the guidelines.
### Table 4.10: Summary of the process reviewed (evaluation processes run parallel at both the NDoH and the SAPC)

<table>
<thead>
<tr>
<th>Activities of NDOH</th>
<th>Activities of GPP Approval (SAPC)</th>
<th>Step Review outcome: Comply / Partially comply/ Does not comply/Not evaluated</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Receive, verify and record application (manual)</td>
<td></td>
<td>Partially comply</td>
<td>Some applications do not have record of received date</td>
</tr>
</tbody>
</table>
| 2. Send a copy of the application to SAPC | b. Receive, verify and record application from NDoH inc. payment | Partially comply/ Does not comply | a. SAPC has record of receipt but NDoH did not have record of sending date  
b. NDoH has record of sending but SAPC did not record receipt date/ allege they did not receive application at all. See Customer Service Officer Figure above showing 47% compliance to processing timelines. |
| 3. Evaluate application and conduct a site inspection | | Not evaluated | Data and standards were not easily accessible to measure, |
| | | | |
| | Manufacturing/ wholesale applications arrange & receive report of site inspection | Partially comply | The step was allocated to Officer, but 92 out of 107 times it was instead handled by Practitioner. |
| | Evaluate application | Does not comply | Time delays in processing. More than three resubmissions were encountered in more than 30% of applications. |
| | Recommendation /non-recommendation | Does not comply | ditto |
| | Final verification | Partially comply | ditto |
| | Finalise certificate | Partially comply | Time delays in processing. |
| | Mail (email & hardcopies) GPP evaluation outcome to NDoH and notify the applicant | Partially comply | ditto |
| 4. Receive GPP outcome | | Partially comply | NDoH requesting resend of mail SAPC’ record showing sent. |
| 5. Hold a Licensing Committee meeting | | Partially comply | Meeting depends on availability of members. |
| 6. Compile the meeting outcome report | | Partially comply | Some data fields were not recorded |
| 7. Finalise application | | Does not comply | Time delays in GPP mostly affected finalising the application (see GPP average time spent) |
| 8. Notify client of the outcome | | Not evaluated | |
The NDoH’s and the SAPC’s current measures/systems were assumed to be adequate to achieve the desired three month average time. However, both organisations acknowledged that significant unforeseen challenges were encountered with the current systems.

4.8 THE PERCEPTIONS OF THE TASK AND PROCESSES OF INVOLVED STAFF (AT THE NDOH AND THE SAPC)

The staff positions listed in Table 4.11a were involved in the task of pharmacy licence approval. Their responses are documented in Table 4.11b. Each of them have handled 2012 application/s and all were still involved in the task during data collection.

The self-administered questionnaire response data contained both closed and open-ended answers to questions, which were captured and manually categorised as indicated in Table 4.11b below.

Table 4.11a: Demographics of the respondents

<table>
<thead>
<tr>
<th>Six Respondents at the NDoH</th>
<th>Number of years in involved licence approval task</th>
<th>14 Respondents at the SAPC</th>
<th>Number of years involved licence approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deputy Director</td>
<td>1 or less</td>
<td>One Senior Managers</td>
<td>5-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One Senior Manager</td>
<td></td>
</tr>
<tr>
<td>Manager</td>
<td>2-5</td>
<td>Three Managers</td>
<td>1 or less</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One Manager</td>
<td>&gt;10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One Manager</td>
<td>5-10</td>
</tr>
<tr>
<td>Two Senior Admin Officers</td>
<td>5-10</td>
<td>Two Practitioners</td>
<td>1 or less</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One Practitioner</td>
<td>2-5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One Practitioner</td>
<td>&gt;10</td>
</tr>
<tr>
<td>One Admin Officer</td>
<td>5-10</td>
<td>One Customer Care Supervisor</td>
<td>5-10</td>
</tr>
<tr>
<td>One Admin Clerk</td>
<td>5-10</td>
<td>Two Customer Care Officers</td>
<td>2-5</td>
</tr>
</tbody>
</table>
### Table 4.11b: Summary of staff perceptions from self-administered questionnaire responses

<table>
<thead>
<tr>
<th>No</th>
<th>Grouped Questions</th>
<th>Question number in the Questionnaire</th>
<th>Respondents: Favourable (Yes/No)</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Do you think it benefits the process that NDoH and SAPC are sharing this task?</td>
<td>1a, 1b</td>
<td>Majority (16) No</td>
<td>Negative</td>
</tr>
<tr>
<td>2.</td>
<td>Is this task given priority it deserves?</td>
<td>1c</td>
<td>Majority (15) No</td>
<td>Negative</td>
</tr>
<tr>
<td>3.</td>
<td>Do employees regard this task important?</td>
<td>1d</td>
<td>Majority (All) Yes</td>
<td>Positive</td>
</tr>
<tr>
<td>4.</td>
<td>Would you say there is good team work?</td>
<td>1e, 1i, 1j</td>
<td>Majority (16) Yes</td>
<td>Positive</td>
</tr>
<tr>
<td>5.</td>
<td>Do you understand the implications of the step/evaluation you perform on this task?</td>
<td>1f</td>
<td>Majority (All) Yes</td>
<td>Positive</td>
</tr>
<tr>
<td>6.</td>
<td>Are you efficient in performing the task</td>
<td>1g</td>
<td>Majority (13) Yes</td>
<td>Positive</td>
</tr>
<tr>
<td>7.</td>
<td>Is the Organisation supportive?</td>
<td>1k</td>
<td>Majority (13) Yes</td>
<td>Positive</td>
</tr>
<tr>
<td>8.</td>
<td>Are appropriate and sufficient resources allocated to do this task?</td>
<td>1l</td>
<td>Majority (14) No</td>
<td>Negative</td>
</tr>
<tr>
<td>9.</td>
<td>Are allocated resources used effectively and efficiently</td>
<td>1m</td>
<td>Majority (17) Yes</td>
<td>Positive</td>
</tr>
<tr>
<td>10.</td>
<td>Do you think the application fee for this task matches the cost of resources used for this task including you as a resource?</td>
<td>1n</td>
<td>Majority (15) No</td>
<td>Negative</td>
</tr>
<tr>
<td>11.</td>
<td>Is the task difficult?</td>
<td>1o</td>
<td>Majority (14) Yes</td>
<td>Negative</td>
</tr>
<tr>
<td>12.</td>
<td>Are you interested in doing this task</td>
<td>1p</td>
<td>Majority (13) Yes</td>
<td>Positive</td>
</tr>
<tr>
<td>13.</td>
<td>Are you coping with the task workload</td>
<td>1q, 1r</td>
<td>Majority (14) No</td>
<td>Negative</td>
</tr>
<tr>
<td>14.</td>
<td>Is your knowledge adequate to do the task?</td>
<td>1s</td>
<td>Majority (12) No</td>
<td>Negative</td>
</tr>
<tr>
<td>15.</td>
<td>Are you well trained</td>
<td>1t</td>
<td>Majority (11) No</td>
<td>Negative</td>
</tr>
<tr>
<td>16.</td>
<td>Does the system notify you that the task is on your step</td>
<td>1w</td>
<td>Majority (13) No</td>
<td>Negative</td>
</tr>
<tr>
<td>17.</td>
<td>Are you often on schedule per guidelines or SOP on performing this task?</td>
<td>1x</td>
<td>Majority (14) No</td>
<td>Negative</td>
</tr>
</tbody>
</table>
Consolidated reasons from open-ended questions

1. Both the NDoH and the SAPC mentioned that the profession did not seem to understand the requirements concerning non-compliance with site and floor plan requirements, which was seen as the major reason for resubmissions (more than 50%). Resubmissions often did not address the shortcomings appropriately, leading to more than the three submissions permitted as shown in Table 4.9.

2. Both the NDoH and the SAPC staff mentioned that the task would be better performed and expedited by one organisation, with one set of resources (cost-effectiveness) and accountability (better prioritised). They believed it was unfair for the clients, as they are currently confused about which organisation to contact for enquiries.

3. The SAPC staff mentioned that there were many disruptions and interruptions experienced by supervisors due to a heavy workload with regular changes of priorities and emerging projects.

4. Both the NDoH and the SAPC perceived that the process was time-consuming due to the many people involved.

5. The SAPC staff said that because of many other applications and tasks, licence applications were not treated with priority.
6. The SAPC staff said that criteria were not clear, and that they had elements of subjectivity resulting in different people interpreting them differently.

7. The NDoH staff mentioned that SAPC takes a long time with GPP evaluation.

8. The NDoH staff would like to move towards electronic systems, instead of manual systems, which are currently in place, to minimise errors.

9. The SAPC staff mentioned that the NDoH send copies to the SAPC that are not as legible as what the client sent, which delays the evaluation process.

The responses in Table 4.11b and in consolidated comments indicate that there are challenges related to the task as perceived by the majority of staff. The challenges were also supported by various sets of results discussed earlier.

**Developments made since 2012 to take into account**

1. The NDoH has appointed a Deputy Director (less than a year ago) who supervises the activities of pharmacy licence approval in the department.

2. The NDoH has published for comment, new criteria (NDoH, 2014), but the SAPC was apparently not consulted. The NDoH and the SAPC have in 2014 scheduled monthly meetings regarding licence approval which was previously not the case. The SAPC mentioned that both organisations were together currently consolidating comments from the public. It is not clear whether the revised criteria will be republished for comment or for implementation.

3. The SAPC Professional Affairs Department consisted of three units. Currently work is shared across them. In one department there are units with two officers, two practitioners, two managers and one senior manager in each. Licence applications (GPP evaluations) are shared equally, e.g. managers share managers’ work and so do others in the three units instead of one unit as was the case in 2012. The responses from the questionnaire indicated that there are still significant challenges due to the existing workload.

4. The SAPC has budgeted to appoint two additional managers in professional affairs to assist/alleviate the workload the current managers have.

5. The SAPC has allocated each unit to be responsible for three provinces. The tasks involved providers of education and training, student registration, student information sessions and internship workshops. The pharmacy licence applications process was not yet allocated per province.
6. The SAPC is working on having most of their applications processed online, to improve their turnaround time;

7. The SAPC has developed a new system which will not allow more than three evaluations, After the third evaluation an application will automatically be rejected;

8. The SAPC senior management holds weekly meetings with the MIS developers regarding improving their systems.

In December, 2014 the SAPC amended the process for applications for pharmacy licences to start at the Professional Affairs Officer instead of Customer Care.
CHAPTER 5
SUMMARY, CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

This chapter includes the summary of study objectives, conclusion, limitations to the study and recommendations to improve the process of pharmacy premises licence approval.

5.2 SUMMARY AND CONCLUSION

The NDoH and the SAPC do not fully adhere to their SOPs and guidelines when processing pharmacy premises licence applications. The total number of applications were 325, NDoH recorded sending 315 of 325 evaluated applications to the SAPC, but the SAPC manual records had 304 whilst electronic records (register and dashboard systems) had 325. In June 2014, there were still 42% of evaluated 2012 applications not finalised by the NDoH data. There were more than three cycles of GPP evaluation by practitioners and managers at the SAPC. Of the 325 SAPC evaluated applications 292 of them were evaluated at least twice with reasons being site/floor plans that did not comply with criteria, i.e. more than 90% of applications were not approved on the first submission. The delays in the current approval processes carried high risks of potential pharmacies not opening, especially those with limited resources for costs such as premises’ leasing and staff recruitment and retention while awaiting approval. This impediment may result in the profession and the public possibly losing confidence in the effectiveness of this service.

The average time spent in GPP evaluation by the SAPC was 252 days. The average overall time spent from receiving an application at the NDoH to finalisation was 316 days. GPP evaluation is a comprehensive and crucial aspect of the approval process. This situation retards progress in expediting and extending access to pharmaceutical care in the country. A revised, accelerated, and readily implementable method is the key to progress in the processing of these applications.

The SAPC staff mentioned that they do not consider this task a priority and applications were likely not be processed on a first come / first serve basis as a result. They stated that they were not coping with their tasks in general. The two units that did not carry out the license approval task before 2013 mentioned that they do not prioritise this task, which is
additional to their already existing high volume of work. The SAPC’s total workforce is approximately 80, with 11 being pharmacists (including the Chief Executive Officer and Chief Operations Officer). The staff complement is either insufficient, inadequately resourced and trained or the systems in place do not favour service delivery.

The NDoH and the SAPC staff believed that there was a level of unfairness towards the client as they were confused as to who to contact. They highlighted that the task would be better performed and expedited by one organisation, with one set of resources (cost-effectiveness) and accountability (better prioritised). In countries such as Kenya, Ghana and the United States of America one organisation, which is usually the Pharmacy Council/Board, carried out the task.

The NDoH and the SAPC staff mentioned that the existing criteria/standards for evaluation are not clear, and are given different interpretations by individual staff members as well as by the applicants. Hence the process becomes subjective rather than objective. If it was objective it may be completed in a shorter time span. The action by senior management in scheduling monthly meetings between the NDoH and the SAPC regarding this task is a positive move for improvements.

It is appropriate that this task is regulated to protect the public, but it must be executed in a way that addresses the needs of both the profession and the public. The increase in the number of pharmacies since 2011 to the end of October, 2014 was 85. The applications for rural areas were only 7% of the evaluated data, which is concerning for equitable distribution of pharmaceutical care in the country. There seemed to be lack of advocacy for access. The time taken to process an application was not justified. The current systems in place inhibit access to pharmaceutical services.

The key reason for the existence of the SAPC is to regulate pharmacy education and practice. Pharmacy practice starts at the licensed pharmacy. No pharmacy licence means no pharmacy, pharmacist, pharmacy support personnel and access to pharmaceutical care for the public. A delay in issuing a pharmacy licence means a delay in improving access.

5.3 LIMITATIONS OF THE STUDY

Of the 325 applications that were evaluated for the year 2012, only 187 (58%) were finalised by the NDoH. At the SAPC, there were only 21 applications still awaiting GPP finalisation. Although there were applications from 2012 that appeared not to be finalised at data collection, it could not automatically be assumed that those 138 (42%) were not finalised at the NDoH. Mostly it was attributed to the manufacturing and wholesale applications that
were awaiting GMP outcome. The number of applications for manufacturing and wholesale that were included in the data were 14 of the 138 finalised applications. These applications constituted 10% of the finalised data and they undergo the GMP/GDWP process of MCC prior to finalisation at NDoH. However GPP process is not affected by this. Human error during manual data capturing at the NDoH may also have been a factor affecting data integrity, especially considering that 42.5% of the 2012 outstanding applications were still to be finalised in 2014.

Also not all applications that the NDoH reported as sent to the SAPC were reflected. Of the 325 that were evaluated, the NDoH data reflected 315 applications sent but SAPC manual record had 304 whilst electronic (register and dashboard systems) had 325. There may be factors affecting data integrity such as human error during manual data capturing (update not yet entered/missed). A breakdown of applications from date of receipt to end date is shown in Table 4.2.

GPP step/staff analysis focused on the time spent by each person in handling an application and the number of permitted resubmissions. The number of resubmissions was evaluated but not fully interrogated since it would have required a longer study period than available. The cause for the reduction of GP pharmacies by 139 since 2011 was also not known. Due to time constrains it could not be established.

5.4 RECOMMENDATIONS

1. The NDoH and the SAPC need to develop clear guidelines/criteria with the site/floor plan requirements that are known and understood by all relevant staff and stakeholders to avoid non-compliance of 90% of applications on first submission.

2. The criteria must rigorously address the concern of maldistribution in concentration of pharmacies in urban areas and continued scarcity in rural areas.

3. The process should assist the applicants to comply by confirming whether shortcoming letters were received. Where necessary a phone call should be made to explain the shortcomings with applicants.

4. One organisation should perform this task to shorten the process and maximise the optimal use of resources (MIS at the SAPC is effective and has consistent records).

5. If point 4. above is not possible, a cost recovery exercise with a reviewed cost- and time-effective process should be carried out for the task for NDoH and SAPC.

6. Regular monitoring and evaluation of this task should be done by management (possibly weekly reviews initially for a while to ensure that the process is fully achievable and implemented in the stipulated time).
7. Sufficient people should be assigned or employed to specialise on this task. This is applicable to the SAPC as they use the “round-robin” system to allocate different applications to staff. The manager’s steps must be reviewed as they are rate-limiting.

8. Advocacy on this service with the aim of increasing the number of approved pharmacy premises per annum. The increase indicated in Table 1.3 is low. Use of roadshows, social media or representatives in different provinces instead of just in Pretoria or a hotline just for this task could improve the situation.

9. Since there are more Cos and CCs applying for pharmacy licences, the NDoH and the SAPC need to approach them to promote pharmacies in the rural areas (one of the reasons of opening pharmacy ownership to lay persons was to have a fair distribution of pharmacies in South Africa and have more pharmacies in rural areas).

10. Applications must be finalised using the first come/first serve principle, with the exception of rural applications which must receive additional focus and effort. Implementation should be audited (especially applications coming from the same area, to avoid late applications receiving approval and earlier ones being declined on the proximity principle).

The current delays in the approval process do not match the need at all. This fact and the relevant data must be brought to the attention of all authorities and stake-holders, possibly in a strategic planning approach whereby all involved accept their responsibilities and carry them out. Regular updates on progress achieved are an important element in moving forward. The process and its required outcomes are too important to be left to chance and the often slow processes of the authorities.


APPENDICES

Appendix 1: NDoH Application Form

Application to licence a pharmacy premises
Section 22 of the Pharmacy Act, 1974 (Act 53 of 1974)

A. Premises to be Licensed

1. Trading Title
   Alternative Title
2. Premises Address

3. GPS Coordinates

B. Classification of Pharmacy

1. Community
2. Institutional
   Private
   State
   Statutory Requirement Y N
3. Wholesale
   Private
   State
4. Manufacturing
5. Consultant

C. Category of Application

1. New
2. Relocation
3. Change in ownership
4. Relocation & change in trading title
5. Change in ownership and trading title

D. Responsible Pharmacist

1. Surname
2. First name/s
3. Registration No. (SAPC)

E. Services and Activities

Submit information required in terms of Sub-regulation 7(2) of the Regulations Relating to the Ownership and Licensing of Pharmacies information neatly typed on a separate page. (This is not required if there is a statutory requirement for the pharmacy in terms of the Regulation 30(h) of Private Hospital Regulations 1980)
### F. Applicant: Sole Trader or Partnership

1. **Surname**
   - First Name/s
   - ID/Permit/Passport No.
   - Registration No./Account No.(SAPC)

2. **Surname**
   - First Name/s
   - ID/Permit/Passport No.
   - Registration No./Account No.(SAPC)

### G. Applicant: Close Corporation or Limited Company

1. **Name of Company / Close Corporation**

2. **Certificate of Incorporation No.**

### H. Applicant: Contact Details of Responsible Person

1. **Title**
   - Mr
   - Ms
   - Mrs
   - Miss
   - Other
   - specify

2. **Surname**

3. **First name/s**

4. **Phone**

5. **Cell**

6. **Fax**

7. **Email address**

8. **Physical Address**

9. **Postal Address**
I. Statutory Declaration

I declare that I am the owner / delegated official of the applicant in respect of this application. I am duly authorised to declare that:

- The contents and all the statements therein made are true.
- All supporting documents are true and accurate.
- The owner is eligible to own a pharmacy in terms of the Pharmacy Act, 1974 (Act 53 of 1974).
- The owner will ensure to ensure compliance to all applicable legislation, regulations and professional obligations.

1. Title
   - Mr
   - Ms
   - Mrs
   - Miss
   - Other
   - Specify

2. Surname

3. First name/s

4. Position held in company

Signature:

Date:

J. Commissioner of Oaths Declaration

Signed and sworn at ____________________________

on this ____________________ day of ____________________, in the year ____________________

the deponent (applicant) having acknowledged that he/she knows and understands the contents of this declaration.

Signature:

Date:

Full name, capacity, address and contact details of Commissioner of Oaths

Please return to Licencing Unit,
4th Floor Civiclace South, Carr Andries & Struben Streets, Pretoria, 0001; or
Private Bag X328, Pretoria, 0001
Phone: 012 395 8202 / 8203 / 8204; Fax: 012 395 8824

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# Application to licence a pharmacy premises

**Appointment of a responsible pharmacist**

**This form must be filled in by the responsible pharmacist and the owner/delegated official of the pharmacy**

## A. Pharmacy Premises

1. Trading Title
2. Premises Address
   - Postal Code

## B. Responsible Pharmacist

1. Name
2. Telephone number
3. Cell number
4. Registration Number

## C. Details of Owner

1. Name
2. Telephone number
3. Cell number
4. Registration number

## D. Declaration

**Owner:**

I, __________________________

hereby declare that the above-mentioned pharmacist has been offered the position of responsible pharmacist at _______________________ Pharmacy in terms of the requirements Section 22 of the Pharmacy Act, 1974.

**Signature:**

**Date:**

**dd / mm / yyyy**

---

**Responsible Pharmacist:**

I, __________________________

hereby declare that I have accepted the position of responsible pharmacist of _______________________ Pharmacy at the above-mentioned premises in terms of the requirements of Section 22 of the Pharmacy Act, 1974.

**Signature:**

**Date:**

**dd / mm / yyyy**
Appendices

REQUIREMENTS FOR FILING A PHARMACY PREMISES LICENCE APPLICATION

IMPORTANT: You must complete and submit all of the requested information. Failure to submit all the required documents will delay the processing of your application. Should the information you provide require more space than provided in the relevant sections, please make photocopies. You will be informed of deficiencies in your application, which must be addressed within 30 days of notification. Failure to do so will render your application null and void and you will be required to complete and submit a new application.

CHECKLIST

All Applicants

[ ] Complete Form PL01: Sections A; B; C; D; E; H; I; J;

[ ] Complete Form PL02 - appointment of a responsible pharmacist; attach proof of current registration with the South African Pharmacy Council;

[ ] Complete Form PL03 – compliance of premises to prescribed norms & standards in accordance with applicable Legislation;

[ ] Professionally drawn site plan;

[ ] Professionally drawn floor plans of pharmacy, drawn according to scale;
   Refer to Section 2.31 of the Good Pharmacy Practice manual, 2010 edition;

[ ] Lease agreement / intent to sign lease agreement;

[ ] Change of Ownership applications: purchase/sale agreement, franchise agreement, current premises licence (original);

[ ] Relocation applications: current premises licence (original);

[ ] Non-refundable application fee of R1000-00, payable to the South African Pharmacy Council:

   Banking details:
   Bank: Standard Bank
   Account type: Cheque account
   Account No.: 011 085 866
   Branch code: 010145
   Beneficiary Ref.: Pharmacy Name
Appendices

**Appendix 2: NDoH Criteria 2001 Census Data**

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**Norms for establishing need – Pharmacies**

These norms will be reviewed annually and compared with trends internationally. International trends were used in the determination of the data outlined in the table below. The data in the table are used as general criteria for establishing need, but other deciding factors could have an impact on the decisions taken by the committee evaluating applications for licensing.

<table>
<thead>
<tr>
<th>1 Pharmacy per Population size</th>
<th>City/town centre</th>
<th>Urban area</th>
<th>Shopping Mall</th>
<th>Rural</th>
<th>Deep Rural</th>
<th>Special circumstances*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 per 5,000 including daily visitors</td>
<td>1 per 5,000</td>
<td>1 per 50,000 foot count per month</td>
<td>1 per 2,500</td>
<td>Special needs clinic, Elderly population, Disabled etc., Taxi Rank, Bus station Railway Station</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximity to other pharmacies</td>
<td>500 metres</td>
<td>500 metres</td>
<td>Not applicable</td>
<td>5 km dependent on topography</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Licensing Committee

Assessment Criteria for Recommendation/Refusal of Licence for Pharmacy Premises

1. Establish minimum norms against which the determination of need for a pharmaceutical service can be measured
   (a) Location of premises – exact geographic, indication on a map
   (b) Benefit to the members of the specific community
   (c) Nature and extent of the service envisaged
   (d) Statutory requirement – refers to private hospitals
      (i) Regulation 30(h) of Private Hospital Regulations 1980 (amended 1993) requires facilities for the immediate supply of all necessary pharmaceutical products i.e. a pharmacy
      (ii) Regulation 7(2) (i) of these regulations states that the Provincial Government does not issue permission to establish a hospital unless the need is satisfied. Therefore need is not a factor in issuing a licence for a private hospital pharmacy.
   (e) Population size – verified using 2001 census
      • City/town centre including daily visitors to the city
      • Urban area
      • Shopping mall – traffic numbers (foot count per month)
      • Rural
      • Deep rural

Special circumstances e.g. special needs clinic; elderly population; disabled; taxi rank; bus station; railway station etc.
   (f) Relationship with existing services – proximity to other pharmacies and/or medical services – distance and numbers of other providers
   (g) Extent of provision of services to persons outside the service area and the nature and availability of pharmaceutical services in the nearby areas e.g.
      (i) Mobile pharmacy service
      (ii) Prescription mail order service
   (h) Special care needs of the community – based on the health status or demographics of the area to be served – proof of competencies

2. Review inspection reports and compare with information supplied by applicant
3. Process transfers of licences to new owners – Section 8 (2) (6) States “A licence issued ........ shall not be transferable to a person not authorised in terms of the Act to own a pharmacy”. Check for Deed of Sale, change in management of company or CC, affidavit authorising ownership of a pharmacy.
4. Recommend and refer the granting of licences for manufacturing, wholesaling and distribution to MCC for which the establishment of need does not apply, and no discussion should be necessary.
5. Request motivation from the applicant due to criteria not being met, or insufficient information.
6. Recommend that the DG grants or refuses a licence for the premises of the pharmacy.
Appendices

Appendix 3: SAPC Criteria

CRITERIA FOR THE EVALUATION IN TERMS OF GOOD PHARMACY PRACTICE OF AN APPLICATION FOR A LICENCE FOR PREMISES WHEREIN OR FROM WHICH THE BUSINESS OF A PHARMACY SHALL BE CARRIED OUT IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974) AS AMENDED

Case Nr: 

Name of Applicant / Pharmacy: 

Type of application: 

Council applies the following criteria in terms of Good Pharmacy Practice for recommendations to the National Department of Health regarding a licence for a premises wherein or from which the business of a pharmacy shall be carried out in terms of the pharmacy act, 1974 (act 53 of 1974) as amended:

Item 2.31.1 - SUPPORTING DOCUMENTATION

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>Complies</th>
<th>Does not comply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A letter of appointment for the responsible pharmacist; NB: No pharmacist may be the responsible pharmacist for more than one pharmacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. A letter of acceptance of the above appointment;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Copy of the site plan of the building, indicating the location of the pharmacy premises in relation to adjoining or surrounding businesses and access to and from the premises; (not road/street map)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Copy of the professionally drawn floor plan indicating the actual layout of the pharmacy premises drawn to scale with exact measurements; (with a legend – see example)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Signed affidavit regarding eligibility, ownership and compliance with standards (must be signed by sole proprietor, all partners of the partnership, all members of the Close Corporation, all shareholders of a Private Company and all Directors of a Public Company);</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. In case of a Close Corporation the latest CK1/CK2 (as approved);</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>7. In case of a company a copy of the Certificate of Incorporation (Change of name if applicable) and the latest CM29 / CoR39;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. If applicable, schedules from the auditors certifying the names of the directors and shareholders;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. A bank guaranteed cheque or proof of payment of the licence application fee made payable to the SAPC.

**Item 2.31.2 - FLOOR PLAN**

The following criteria must be clearly indicated in the submitted copy of the professionally drawn floor plan indicating the actual layout of the pharmacy premises drawn to scale with exact measurements: (see examples attached (if, where & when applicable) + all areas, sizes to be in a legend on the floor plan)

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>Complies</th>
<th>Does not comply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The size of the premises (m²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. The size of the dispensary (m²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. All entrances and exits of the pharmacy;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. All entrances to the enclosed areas in the pharmacy e.g. admin office, manager’s office, dispensary, kitchen, private area and consultation area, toilets (m² sizes of all enclosed areas)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. A separate facility for washing hands;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. A separate facility for compounding of extemporaneous preparations and cleaning of equipment;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Sufficient and adequate lighting;</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>8. A suitable waiting area;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. A fridge for heat sensitive pharmaceuticals and vaccines;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. A suitable separate private room for private consultation of patients;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. A suitable consultation area for the provision of screening and monitoring tests, where applicable;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. All Scheduled medicines to be stored / displayed inaccessible to the public;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. A dispensing counter for prescriptions and pharmacist initiated prescriptions, with a suitable semi private area for each dispensing point; the dimensions of the dispensing counter and semi-private area are to be</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
indicated on the floor plan and are to comply with the following requirements:

(i) Height of partitioning of the semi-private area from floor – 1800mm

(ii) Dispensing point: between 600 - 900mm deep & Dispensing point: by 1000mm wide

(iii) Partition protruding: 400mm from edge of the counter (to the front side)

NB: S1 and S2 counter area must be one continuous entity with dispensary and the above criteria apply to both counters.

### Item 2.31.3 - Trading Title

These criteria apply to the use of a title, trading title, name, description, brand name or logo (referred to as the “name”) used with respect to a community or an institutional pharmacy situated in a private or a public health facility.

In terms of the requirements of GPP the SAPC shall regard the use of following names as unacceptable -

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>Complies</th>
<th>Does not comply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The use of the same or a similar name, including a name that sounds similar but is spelt differently, as that of another pharmacy if such pharmacies do not have the same owner;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Any name which is likely to be considered offensive;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. A name that is calculated to suggest that the pharmacy in question is superior to another pharmacy or pharmacies;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. A names which creates the impression that medicines are being sold at discounted prices;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. A name which may be misleading to the public;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. A name that is not associated with or does not belong to the pharmacy concerned;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. A name that is calculated to suggest that the professional skills or ability or facilities for the rendering and supply of services which form part of the scope of practice of a pharmacist are superior or better than those of other pharmacies or pharmacists;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8. A name that is calculated to suggest that a pharmacy is associated with, belongs to or is in any way connected with a body corporate, firm or business, when not owned or part owned by that body corporate, firm or business;

9. Any name which is in contravention to the Pharmacy Act 53 of 1974.

**GENERAL**

**Item 2.31.4 Pharmacy in another Business (as indicated on the floor plan):**

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>Complies</th>
<th>Does not comply</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) The pharmacy premises is clearly identified and demarcated from the premises of any other business or practice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) The demarcation is permanent, solid and closed-off at all times, (which demarcation may be inter alia, brick and mortar, aluminium, steel, glass, dry wall or wood partition).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) The demarcation is from floor to the ceiling height and must enclose all areas attached to the pharmacy, (viz; the waiting area, the clinic, the semi-private area and the private area).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) The pharmacy must have a single point of entry and a Single point of exit in compliance with the Occupational Health and Safety Act, 85 of 1993 (OHSA).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) In order to comply with the requirement of accessibility to pharmaceutical services, a pharmacist must have an unfettered 24 hour access to the pharmacy.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Item 2.3.1.6**

The application has been signed and sworn in the presence of a Commissioner of Oaths.
Appendices

Appendix 4: SAPC Process flow prior to 2013 - GPP evaluation of a pharmacy licence application

The first process flow refer to a valid application which meets all requirements (one to six). The second process indicates an application with shortcomings (one to ten).

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Customer care receives an application(s) from NDoH and verifies all documents for completeness and correctness, then uploads application. Finance clerk &amp; manager verify R1000 payment.</td>
</tr>
<tr>
<td>2.</td>
<td>Practitioner receives application &amp; evaluates the case according the 13 criteria items that are compulsory as prescribed in the GPP 4th edition of 2010. Officer will arrange inspection.</td>
</tr>
<tr>
<td>3.</td>
<td>When the case is compliant, the practitioner sends it to the manager for approval.</td>
</tr>
<tr>
<td>4.</td>
<td>The manager sends it to the Senior Manager for final verification (If manager see S/C it goes back to step 3 in black print)</td>
</tr>
<tr>
<td>5.</td>
<td>The recommendation letter is approved &amp; signed by the Senior Manager &amp; is handed over to NDoH (practitioner email NDoH&amp;client, Mail clerk courier to NDoH&amp;client) (If Snr mx see S/C it goes back to step 3 in black print)</td>
</tr>
<tr>
<td>6.</td>
<td>Practitioner hands it to Customer care for NDoH collections</td>
</tr>
<tr>
<td>7.</td>
<td>If shortcomings (S/C) are identified, the manager approves a letter stipulating the shortcomings to be corrected by the client</td>
</tr>
<tr>
<td>8.</td>
<td>The regret letter and the GPP non-recommendation letter are signed by the Senior Manager</td>
</tr>
<tr>
<td>9.</td>
<td>A regret letter is sent out to the client and a copy sent to NDoH</td>
</tr>
<tr>
<td>10.</td>
<td>The non-recommendation letter is sent to the NDoH</td>
</tr>
</tbody>
</table>

The process below begins with and includes steps one and two mentioned in the above process:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>Manager sends back the signed S/C letter to the practitioner &amp; the practitioner sends an email/ fax to the client and by post</td>
</tr>
<tr>
<td>4.</td>
<td>The client is advised to respond to the shortcomings within 21 working days of receiving the shortcomings letter. If the client responds in time, it goes back to step 2 and follows either white or black print steps</td>
</tr>
<tr>
<td>5.</td>
<td>If there is no response to the S/C’s letter a follow-up letter is sent after 21 working days.</td>
</tr>
<tr>
<td>6.</td>
<td></td>
</tr>
</tbody>
</table>
Appendices

Appendix 5: SAPC 2013 process costing

Estimated resources involved and timelines (applicable in 2010-2012 as well)

The table below is divided into personnel cost per job title & the average time spent by that person on one licence application for GPP evaluation

<table>
<thead>
<tr>
<th>Logistics Clerk</th>
<th>Time per hour</th>
<th>Customer Care Agents</th>
<th>Time per hour</th>
<th>Practitioner</th>
<th>Time per hour</th>
<th>Manager</th>
<th>Time per hour</th>
<th>Senior Manager</th>
<th>Time per hour</th>
<th>Finance clerk</th>
<th>Time per hour</th>
<th>Finance Revenue manager</th>
<th>Time per hour</th>
<th>Senior logistics officer</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>R76.00</td>
<td>0.33</td>
<td>R118.00</td>
<td>0.33</td>
<td>R150.00</td>
<td>4.00</td>
<td>R289.00</td>
<td>3.00</td>
<td>R355.00</td>
<td>1.00</td>
<td>R118.00</td>
<td>1.00</td>
<td>R191.00</td>
<td>1.00</td>
<td>R112.00</td>
<td>R2 815.22</td>
</tr>
</tbody>
</table>

The application fee for a Pharmacy premises licence is R1, 000.00 which both the South African Pharmacy Council (SAPC) and the National Department of Health (NDoH) share. The cost table lists the SAPC resources involved.
Appendix 6: NDoH pharmacy premises licence approval process

1. Receive application: by either of the two clerks (level 5) involved, check against checklist for requirements, e.g. need the affidavit, open a file then make copies to send to SAPC.
2. Admin Officer (level 7), Quality Control gathers the information, prepares documents & adds to the list of inspections due.
3. Inspection to the site is conducted (by either of the two deputy directors. NDoH has only two inspectors for this task).
4. Inspection report is prepared for the committee by Admin Officer (level 7).
5. Committee meeting takes place (Chaired by Director, attended by inspector and Cluster Managers from legal, district health, MCC and hospital services clusters).
6. Clerk (level 5) captures the Committee decision.
7. Senior Admin Officer (level 8): finalises and conducts Quality Control on database & licence.
8. Deputy Director approves data and communication, then forwards it for final verification to Director.
9. Director verifies and sends it to the Director General delegate.
10. Cluster Manager (DG delegated) signs.
11. Appeals procedure is in place (ad hoc appeal committee. The committee is appointed by the Minister

The application outcome is communicated to the public (South African citizens) and an appeal can be lodged.

Once an application is received and is complete and loaded on to the system it should take approximately two weeks to send to the SAPC.

On average SAPC receives 60 applications per quarter, the Committee sits once per month.

Source: Meeting notes between the SAPC and the NDoH on 10 July, 2013
Appendix 7a: Letter to CEO at Pharmacy Council for permission to conduct a study

Letter to Chief Executive Officer

UNIVERSITY OF LIMPOPO
Medunsa Campus
Department of Pharmacy

P O Box 218
Medunsa
0204

Mr Amos Masango
SA Pharmacy Council
Private Bag 40040
Arcadia
0007

Dear Sir

Re: Permission to conduct a study at the South African Pharmacy Council

I am an MSc (Med) Pharmacy student at the University of Limpopo, Medunsa Campus. I have to conduct a research project, as part of the requirements for my post-graduate qualification. The title of my study is: The review of the South African pharmacy licence approval process over the period 01 January 2012 to 31 December 2012, and relevant staff (at SAPC and NDoH) perceptions of the process" I hereby kindly request permission to conduct the study in your institution.

Attached please find a copy of the protocol, which will be submitted to the Medunsa Campus Research and Ethics Committee for ethical approval.

I trust that you will find the above in order. Please feel free to contact me or my supervisors, should you require additional information.
Yours faithfully

Daphney Fafudi
MSc (Med) Student
Cell: 0712669263
26 August 2013

Prof RS Summers (Supervisor)
Tel: 012 521 5866/ 08283830445
Appendices

Appendix 7b: South African Pharmacy Council letter of permission to conduct a study

Ms D. Fafudi
P.O. Box 102341
MORELETA PLAZA
0167

OUR REFERENCE
TA Masango

DATE
27 August 2013

Dear Ms Fafudi

PERMISSION TO CONDUCT A STUDY AT THE SOUTH AFRICAN PHARMACY COUNCIL

Thank you for your letter dated 27 August 2013, the contents of which have been noted.

Please be advised that permission is granted for your study titled: The review of the pharmacy licence approval process over the period from 01 January 2010 to 31 December 2012, and staff perceptions of the process.

Yours faithfully

TA MASANGO
REGISTRAR/CEO

/ag

ALL CORRESPONDENCE TO BE ADDRESSED TO THE REGISTRAR
Appendices

Appendix 8: Respondent information leaflet

Dear Respondent

Please read this information about the study and feel free to ask any questions should you need any clarity before deciding to take part in the study.

I am an MSc (Med) student from the University of Limpopo, Medunsa Campus. I am going to conduct a study on the review of South African pharmacy licence approval process and relevant staff perceptions of the task and process.

Aim of the study

To describe the service for pharmacy premises licence approval during the period 01 January 2012 to 31 December 2012, and assess relevant staff (at SAPC and NDoH) perceptions of the task and process.

Objectives of the study

- To document and carry out a critical review of the steps involved in processing applications for pharmacy premises licence.

- To determine whether the application process complies with the current SOPs and guidelines for pharmacy premises licence approval.

- To identify the factors which cause deviations from the SOPs and guidelines for pharmacy premises licence approval.

- To identify if the process of pharmacy premises licence approval ensures optimal response the South African country’s needs in terms of access to pharmaceutical care

- To describe relevant staff (at SAPC and NDoH) perceptions of the task and processes for pharmacy premises licence approval.

You will be requested to complete a questionnaire, which will take approximately 10 minutes. Your responses will be anonymous and all information will be treated confidentially. Participation in the study will be voluntarily and you can withdraw from the study at any time if you wish to do so.

64
If you agree to participate in the study, you will be required to sign a consent form to indicate your willingness to participate. If you agree to participate in the study, you will be required to sign a consent form to indicate your willingness to participate.

The study has been approved by the University of Limpopo, Medunsa Campus Research and Ethics Committee and the Chief Executive Officer of the South African Pharmacy Council in consultation with the National Department of Health.

Please feel free to contact myself on 083 821 9901 or my supervisor, Prof RS Summers on 012 – 521 5903, if you have any further questions regarding this study.

Kind regards

_______________________
Daphney Fafudi
Researcher
UNIVERSITY OF LIMPOPO (Medunsa Campus) CONSENT FORM

Statement concerning participation in a /Research Project*

Title of study: Title of study: A review of the South African pharmacy licence approval process at the South African Pharmacy Council and the National Department of Health.

I have read the information the aims and objectives of the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurised to participate in any way.

I understand that participation in this Study is completely voluntary and that I may withdraw from it at any time and without supplying reasons.

I know that this Study has been approved by the Medunsa Research Ethics Committee (MCREC), University of Limpopo (Medunsa Campus) / the South African Pharmacy Council in collaboration with National Department of Health. I am fully aware that the results of this Study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Study.

........................................... ....................................................
Name of respondent                  Signature of respondent

........................................... ....................................................
Place                                Date                           Witness
### Appendix 10: Retrospective pharmacy premises licence application approval data collection form

<table>
<thead>
<tr>
<th>Category</th>
<th>Province</th>
<th>Ownership</th>
<th>Application</th>
<th>SAPC</th>
<th>NDoH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community</td>
<td>Limpopo</td>
<td>Independent</td>
<td>Date in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institute</td>
<td>SAPC</td>
<td>Corporate</td>
<td>Date out:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHP shortcomings</td>
<td>Gauteng</td>
<td>Pharmacist</td>
<td>Duration of application:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing</td>
<td>North West</td>
<td>Non-Pharmacist</td>
<td>Outcome:</td>
<td>Recommendation</td>
<td>Approval</td>
</tr>
<tr>
<td>Consultant</td>
<td>Western Cape</td>
<td>Non-Pharmacist</td>
<td>Outcome:</td>
<td>Non-Recommendation</td>
<td>Non Approval</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Comments</td>
<td>Comments</td>
</tr>
<tr>
<td>Supporting documents</td>
<td></td>
<td></td>
<td></td>
<td>Inspection findings</td>
<td></td>
</tr>
<tr>
<td>Floor plans</td>
<td></td>
<td></td>
<td></td>
<td>application form</td>
<td></td>
</tr>
<tr>
<td>Pharmacy in another business</td>
<td></td>
<td></td>
<td></td>
<td>norms for</td>
<td></td>
</tr>
<tr>
<td>Trading</td>
<td>SAPC GPP shortcomings</td>
<td></td>
<td></td>
<td>Outcome</td>
<td>Approval</td>
</tr>
<tr>
<td>Staff title</td>
<td>Date in</td>
<td>Date out</td>
<td>Date in</td>
<td>Date out</td>
<td>Date in</td>
</tr>
<tr>
<td>-------------------------------------</td>
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</tr>
<tr>
<td>At SAPC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Logistics clerk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customer care agent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finance revenue clerk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior logistics officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Practitioner 1&lt;sup&gt;st&lt;/sup&gt; step</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>manager</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Practitioner 2&lt;sup&gt;nd&lt;/sup&gt; step</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior manager</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manager 2&lt;sup&gt;nd&lt;/sup&gt; step</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Practitioner 3&lt;sup&gt;rd&lt;/sup&gt; step</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior admin officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applicant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At NDoH</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin clerk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior admin clerk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deputy Director</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Director</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendices

Appendix 11: Self-administered structured questionnaire

Title of study: A review of the South African pharmacy licence approval process at the South African Pharmacy Council and the National Department of Health

MSc (Med) Pharmacy, Department of Pharmacy, University of Limpopo, Medunsa Campus (UL)

You are requested to complete this questionnaire in order to help the researcher obtain information on your perception of the pharmacy licence approval process. Please mark the appropriate box or give details where appropriate. Please return the form to the researcher who will collect the form within 120 hours. Information will be treated in confidence and the source will not be identified in the final report (i.e. everything will be handled anonymously). Completion of this questionnaire indicates that you consent to participate in the study.

1 General information regarding the pharmacy premises licence approval task/function

PLEASE SELECT ONE OF THE BOXES PROVIDED

Do you work for the National Department of Health (NDoH) / South African Pharmacy Council (SAPC)?

☐ NDoH
☐ SAPC

Tick your job title below.

☐ Senior Manager ☐ Deputy Director ☐ Manager
☐ MC Practitioner ☐ Senior Officer ☐ Customer Care
 Orig
☐ Admin Clerk ☐ Logistics clerk ☐ Other
 (Specify) ……..

Tick one of the following boxes with regard to how long you have been performing this function/task (pharmacy premises licence application evaluation process).

☐ 1 year or less ☐ 2-5 years ☐ 5 years ☐ 5-10 years ☐ More than 10 years

If you ticked 1 year or less performing this function/task, tick one of the following boxes:

☐ Had not yet joined the organisation
☐ Was in a different unit/ performing different tasks
 ☐ Other (Specify) ……

a. What are your thoughts about the NDoH and SAPC sharing this task as currently occurs?
Appendices

b. Do you think sharing the task has benefits to the process of pharmacy premises licence approval?
   ☐ Yes
   ☐ No

   If your answer is ‘No’, state the reason/s in the space provided.

   ______________________________________________________
   ______________________________________________________
   ______________________________________________________

c. Do you think your organisation is giving this function/task the priority it deserves?
   ☐ Yes
   ☐ No

   If your answer is ‘No’, state the reason/s in the space provided.

   ______________________________________________________
   ______________________________________________________
   ______________________________________________________

d. Do you think the employees involved in this task regard this task important?
   ☐ Yes
   ☐ No

   If your answer is ‘No’, state the reason/s in the space provided.

   ______________________________________________________
   ______________________________________________________
   ______________________________________________________

e. Do you think the employees involved in performing this task work as a team?
   ☐ Yes
   ☐ No

   If your answer is ‘No’, state the reason/s in the space provided.

   ______________________________________________________
   ______________________________________________________
f. Do you understand the implications of the step/evaluation you perform on this task?
   ☐ Yes
   ☐ No

   If yes, what do you think are the implications?
   ______________________________________________________
   ______________________________________________________
   ______________________________________________________

   g. How efficient would you say you are in performing this task?
   ☐ Highly efficient ☐ Efficient ☐ Inefficient ☐ Highly inefficient

   h. To whom do you report (the supervisor's title, not his/her name) with regard to this function/task?
   ______________________________________________________
   ______________________________________________________
   ______________________________________________________

   i. How efficient would you say your supervisor is, in performing this task?
   ☐ Highly efficient ☐ Efficient ☐ Inefficient ☐ Highly inefficient

   j. Rate the quality of the interaction between you and the supervisor regarding the task.
   ☐ Excellent ☐ Good ☐ Fair ☐ Poor ☐ Very poor

   k. Rate the support system in place from your organisation regarding this task.
   ☐ Excellent ☐ Good ☐ Fair ☐ Poor ☐ Very poor

   State the reason/s for your response in the space provided.
   ______________________________________________________
   ______________________________________________________
   ______________________________________________________

   l. Do you think there are appropriate resources for this task to be performed efficiently (like equipment, anything you need to do this task including people needed)?
   ☐ Yes
   ☐ No

   If your answer is 'No', state the reason/s in the space provided.
m. Do you think resources in place to do this task (like equipment, anything you need to do this task including people) are used effectively and efficiently

☐ Yes
☐ No

If your answer to is ‘No’, state the reason/s in the space provided.

n. Do you think the application fee for this task matches the cost of resources used for this task including you as a resource?

☐ Yes
☐ No

If your answer to is ‘No’, state the reason/s in the space provided.

o. Rate the level of difficulty of this task.

☐ Very easy ☐ Moderately easy ☐ Not easy ☐ Difficult ☐ Very difficult

p. Rate the level of interest you have when doing this task.

☐ Very interested
☐ Moderately interested
☐ Not interested

q. Are you able to maintain balance (good performance) between this task and other tasks?

☐ Yes
☐ No

r. How do you find the workload of this task?
Appendices

☐ Very easy to manage  ☐ Moderately easy to manage
☐ Not easy to manage  ☐ Difficult to manage
☐ Very difficult to manage

s. Rate your knowledge regarding the SOP and guidelines for this task.
   ☐ Very high    ☐ High    ☐ Intermediate    ☐ Low    ☐ Very low

t. Do you think you are well trained for this task?
   ☐ Yes
   ☐ No
   If no, please elaborate?
   _______________________________________________________________________
   _______________________________________________________________________
   _______________________________________________________________________

u. List two things you find most challenging in processing/evaluating an application.
   _______________________________________________________________________
   _______________________________________________________________________
   _______________________________________________________________________

v. How do you think you can reduce these challenges?
   _______________________________________________________________________
   _______________________________________________________________________
   _______________________________________________________________________

w. Does the system (process) notify you as soon as an application is ready for you to perform this task?
   ☐ Yes
   ☐ No
   If your answer is 'No', how do you know that an application is ready for you to evaluate/perform your task?
   _______________________________________________________________________
   _______________________________________________________________________
   _______________________________________________________________________

x. Are you on schedule with the evaluation of each licence application according to the guideline timelines?
y. Does your unit/department involve you when revising the guidelines/Standard Operating Procedures?
   ☐ Yes
   ☐ No

z. If you could make decisions to improve this task, what would they be?

| 2 Straightforwardness of the pharmacy premises licence application forms |
|---------------------------------------------------------------|-----|-----|
| a. Do you think the applicants understand the requirements?  | ☐   | ☐   |
| b. Do you think the pharmacy premises licence application requirements are clear and simple enough for the applicant to understand? | ☐   | ☐   |
| c. Do applicants often respond appropriately to the shortcomings in their first response? | ☐   | ☐   |
| d. Have there been any significant changes in the task structure during the period 01 January 2012 to 31 December 2012? | ☐   | ☐   |

   If yes, list them and briefly describe the changes.

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
e. Which area/section of the application requirement is most challenging for applicants to interpret correctly? Please insert your answer in the space below

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Thank you for completing this questionnaire.
Appendix 12: MREC Approval

UNIVERSITY OF LIMPOPO
Medunsa Campus

MEDUNSA RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE

MEETING: 02/2014

PROJECT NUMBER: MREC0467/2014/ PG

PROJECT:

Title: A review of the South African pharmacy licence approval process and relevant staff perceptions of the task and process

Researcher: Mrs M D Fathudi
Supervision: Prof KG Summerson
Co-supervisor: Mrs E Heilberg
Hospital Superintendent: Mr A Maseko Registrar – South African Pharmacy Council
Department: Pharmacy
School: Health Care Sciences
Degree: MSc (Med) Pharmacy by Coursework

DECISION OF THE COMMITTEE:

MREC approved the project.

DATE: 08 March 2014

Note:

1) Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.

2) The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.