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The impact of Human Resources on the effective and efficient registration and regulation of medicines in South Africa

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Introduction: The SAHPRA, South Africa's answer to the regulation and registration of medication

What is the South African Health Products Regulatory Authority?

South Africa is in need of a fully functional public Medicine Regulatory Authority (MRA). Currently the Medicines Control Council (MCC) exists as a unit within the National Department of Health. The MCC oversees the manufacture, marketing, sale and distribution of medication in South Africa, as per the standards set out in the Medicines and Related Substances Amendment Bill, (Act 101 of 1965). The South African Government has been trying to establish the MCC as the South African Health Products Regulatory Authority (SAHPRA) for the past decade. The SAHPRA will be established as Schedule 3A Public entity. This would mean that the MCC will no longer be a part of the National Department of Health and will have greater autonomy over the activities within the organization.

Why is a medicines regulatory authority important?

As per clause 2A of the Medicines and Related Substances Amendment Bill, SAHPRA will be responsible for the "monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest." The most important part of the above statement is "in the public interest". This emphasizes that there will be a large amount of trust placed in the SAHPRA by South African citizens especially in terms of the safety of the products registered. The Medicines and Related Substances Amendment Bill, (Act 101 of 1965) is central to the functioning of SAHPRA. In November 2015, the Select Committee on Social Services approved the amendment bill so as to allow SAHPRA to strengthen the above mentioned functions in South Africa.

The SAHPRA will not only register orthodox medication but complimentary medication, medical devices, in vitro diagnostics (IVD) and at a later stage, African Traditional Medicines. The last 3 medication types have not been regulated in South Africa before and these are therefore explained in great detail in the amendment bill.

What does this Performance and Expenditure Review intend to do?

This performance and expenditure review will detail the policy and institutional analysis of the SAHPRA, and link the performance of the MCC to the objective stated in the policy. Following this, the expenditure of key cost drivers that have a direct impact on the achievement of the policy objectives will be presented, and lastly, a costing model on the key cost drivers and recommendations for savings will be investigated.

What are the challenges faced by the MCC?

The current issue existing at the MCC is the relatively small staff component. This has a direct impact on the ability of the MCC to process applications in a fast and timeous manner; this has resulted in a large backlog of applications. Due to the SAHPRA not being established as a public entity yet, the MCC does not have the ability to keep the revenue it generates from the registration and regulation of medications in South Africa. The inability to retain revenue therefore is a key factor in the MCC not being able to afford the optimum level of staff which has resulted in the backlog. The two vital aspects of the SAHPRA being able to generate large amounts of revenue are namely; the amounts/fees charged for registration and the demand for the registration of these products (or volumes of applications). Due to the low capacity of staff at the MCC, they utilize their own staff and also outsource evaluators to examine the dossiers for the drugs. Both of these costs (current employees and consultants) will be examined in the expenditure analysis.

The study focuses on the human resource components that will allow the SAHPRA to fulfill its mandate of registering medications in South Africa.

Important questions examined during analysis will be:

- The number of the current personnel employed at the MCC and how it is likely to change over the short and medium term once the MCC becomes SAHPRA?
- What is the current personnel budget of the MCC and how it is likely to change over the short and medium term when the MCC becomes SAHPRA?
- How the funding model of the SAHPRA is likely to change and what is a realistic income for the SAHPRA likely to be?

Institutional Landscape: The funding flows, stakeholders and programme elements

Funding Flows from the National Treasury to the MCC and the SAHPRA:

Figure 1 in the Excel workbook "Logic Frame work and funding flows 12 July 2016" will show the current funding flow mechanism of the MCC. Funds from the National Revenue Fund (NRF) flow from National Treasury to the National Department of Health (NDOH), via the sub-programme "Pharmaceutical Trade and Product Regulation". This sub-programme is found under Programme 6 under vote 16 in the budget.

The NDOH then distributes these funds to the MCC. This is the budget of the MCC and is used for expenditure. As stated above, the MCC also generates revenue from the registration of medications as shown in the Figure 1. However as per the PFMA no department is allowed to keep the revenue generated. Therefore these funds are given back to National Treasury and are redistributed via the NRF. However as per the PFMA, schedule 3A public entities have the ability to retain the surplus produced with the approval of the National Treasury.

Figure 2 in the Excel workbook "Logic Frame work and funding flows 12 July 2016" shows the funding flow for the SAHPRA and it follows the same sequence as in Figure 1 with two key exceptions. Firstly the funding for the SAHPRA now flows through the "Public Entities Management" sub-programme and secondly, the SAHPRA will have the ability to retain the funds generated through the registration of new medications, thus these funds will not flow back into the NRF. The budget of the SAHPRA will therefore be increasing on an annual basis due to; the revenue generating ability of the SAHPRA, its ability to retain the revenue it makes from the annual registration of medications, an increased staff component and increased capacity of the staff to process applications in a timely manner. It should also be noted that in the future, new revenue generating steams will be added such as traditional African medicines. National Treasury will continue to provide funding to the SAHPRA via the Public Entities Management Subprogram. As the SAHPRA generates its own revenue it will become self-sustaining.

The generation of revenue by the SAHPRA, in future years, may provide an option for savings for National Treasury as the budget given to the SAPPRA may decrease on a yearly basis as the SAHPRA may have the ability to self-fund. National Treasury may consider decreasing the budget

at a set rate each year. The funds may be placed into the NRF and used for other competing priorities. It should be noted that the funding from the National Treasury should not disappear in totality as this would mean that the government (specifically National Treasury) will have no influence over the SAHPRA.

How the MCC and SAHPRA will generate its revenue:

The MCC currently generates fees at three stages during the regulation process. The first is the registration fee (this is a small amount paid when an application is handed in and takes care of the fees associated with the administration.) Once the application has gone through the process and the drug is ready to be registered, a larger post screening fee is paid. Finally once the drug has been registered with the MCC, the manufacturer pays an annual retention fee in order for the company to maintain the registration of the drug. During consultations with the MCC and another consultant, the view is that the registration fee may be increased in the coming years to match or closely mimic the fees in developed countries due to the market for these drugs being quite large in South Africa. Other African countries also rely on the MCC to register their drugs, and this gives the SAHPRA access to an even wider market for revenue generation. The same processes will be followed by the SAHPRA.

The focus of this study is the costing of the employees of the SAHPRA, however, in the future, the revenue generating potential of the SAHPRA should be examined through a revenue generation model. This will be used to do revenue forecasting. It is important that the possible revenue generating capacity of the SAHPRA be taken into account especially in the budget process as this will allow National Treasury to budget and to revise its allocation to the SAHPRA, in a more efficient way. It is recommended that this model take into account the registration and retention fees for medications charged internationally as the market for pharmaceuticals is large in South Africa. This may allow the SAHPRA to charge fees on par with many European Countries.

The overview of the functioning of the MCC/SAHPRA:

Figure 3 in the Excel workbook “Logic Frame work and funding flows 12 July 2016” depicts the birds-eye view of the MCC with the individuals responsible for the submissions of the documentation to the MCC or the SAHPRA, and the end-users of the registered products. The

largest and most significant end-user would be the public. As stated above the functions carried out by the MCC or SAHPRA are in the interest of the public.

Figure 4 in the Excel workbook "Logic Frame work and funding flows 12 July 2016" depicts the stakeholders involved in the processes feeding into the MCC/SAHPRA. These are the National Treasury and the National Department of Health (NDOH). The National Treasury provides funds to the MCC via the NDOH and the NDOH over sees the activities of the SAHPRA. The MCC currently has a fast track process for priority drug registration and the NDOH has the final say as to which drugs enter the fast track process. The MCC/SAHPRA has the duty of monitoring many functions such as the registered products as well as the quality standards of the manufactures that have been issued licenses (by the NDOH) to manufacture certain drugs. Under the MCC there are two employee categories; the current MCC staff and the consultants. The MCC employees are responsible for the creation of the relevant documentation for the establishment of the SAHPRA, while the consultants (evaluators) are responsible for reviewing the dossiers (documents on each drug as part of the registration process). The program elements for each stakeholder is given in the Figure 4. .

Assessment of MCC performance information and a logic framework for the establishment of the SAHPRA:

<u>Performance Information:</u>

Initially the Strategic Plan and Annual Performance Plan of the National Department of Health were be examined for performance indicators. Unfortunately, only two indicators existed in the NDOH Strategic Plan 2014-2019 and 2014-2015 Annual Report were not very descriptive or useful. These can be seen in below in Table 1. These indicators deal with the establishment of the SAHPRA and not the functions of the MCC. The 2012/13 NDOH Annual report shows that the MCC tried to decrease the average time taken to register priority medication for HIV and TB. It is suggested that the following indicators be added to the reporting as these would be more descriptive of the progress made in the registration of medications, for example the number of new registrations completed a month, number of clinical trials being conducted or completed.

Such indicators will be useful as there is currently a backlog at the MCC regarding the applications for new medicine registrations. Other suggested indicators can be found in the logical framework.

During the meeting with the MCC on 1 June 2016, the MCC indicated the average timeframe for the registration of new chemical entities and generic drugs. According to the MCC the time frames are on par with international standards. From the time of evaluation it takes an average of 3 years to register an orthodox new chemical entity and 2 years for a generic drug. No information is available currently for complimentary medication as these have not been regulated by the MCC. One issue of concern is the difficulty experienced by the MCC to create performance contracts with the evaluators. As a result the evaluators are taking longer to process these dossiers and related documentation, which is adding to the backlog at the MCC. One key area of focus of the MCC on the road to the establishment of the SAHPRA is the creation of these contracts to aid in the monitoring and evaluation of the progress made by the evaluators. It can therefore be understood why the MCC started to focus on priority medications as dictated by the situation in the health space.

Logical Framework:

The logic frame work produced (Figure 5 in the work book titled "Logic Framework and funding flows") has the goal for the SAHPRA as "Effective and efficient registration of medications in South Africa" the most important aspects of the logic frame work would be: 1) The submission of the required documentation to the National Treasury's Public Entities Governance Unit as this would allow for the MCC to fulfill the legal requirements (as per the rules set by this unit) for the SAHPRA to be a public entity. It is only after the establishment of the SAHPRA that the body will be able to retain revenue and employ more staff with an optimum mix (including trainee evaluators and current MCC evaluators). 2) During the meeting with the MCC it was noted that once the documentation for review reached the evaluator (who is a consultant), it takes a long time to be reviewed, which may be attributed to the lack of performance contracts at present. Therefore this will be an area of work in the future.

The difficulty in the lack of good performance indicators and performance contracts influences the fast and effective regulation of the drugs leading to the back log. Under the outcomes, work

needs to be done to create policies and standard operating procedures for the regulation of complementary medication in South Africa (this is an untapped revenue stream as these medications have not been regulated before). Refer to figure 5 for a more in-depth logical frame.

Assessment of the MCC Expenditure:

The initial Expenditure Analysis (2012/13 to 2015/16) was done using the BAS data. The 2016/17 (until May 2016) data was drawn from Vulindlela. This was used as an opportunity to check the previous year's BAS data against the Vulindlela data; the data sets were found to be the same. Data was filtered to the Pharmaceutical and Trade Regulation sub sub-programme.

What are the key cost drivers of MCC expenditure?

The expenditure data in the sub sub-programme was organized into the expenditure categories. It was found that compensation of current (MCC) employees, Board Member costs and business advisory consultant costs made up close to 79% of the total expenditure. The other expenditure categories made up an average of 21% of annual expenditure from 2012/13 to 2015/16. The approach was then to use the 80:20 rule (focusing on the 20% of expenditure categories that make up or drive 80% of expenditure in a programme).

Table 1 below demonstrates the total expenditure each year on the key cost drivers. The high costs on consultants are directly linked to the MCC having a small staff component, with a low capacity to carry out the work needed to register and regulate medications in a timely manner. Compensation of employees (COE), Board Member costs and business advisory consultant costs are therefore not only cost drivers but are vital components for the MCC and the SAHPRA to achieve its policy objectives.

The issue of a small staff compliment and low capacity was discussed at length in the meeting with the MCC and twop solutions were suggested by the MCC. Firstly, the MCC plans to retain current staff and employ additional staff with the correct qualifications and expertise to grow in-house capacity once the SAHPRA is established. Secondly, as mentioned in the performance information section, there are currently no performance-based contacts with the evaluators. SAHPRA will have the autonomy to create such contracts and hold in-house evaluators and other

out sourced consultants accountable for producing results at a faster pace. These contacts are of high importance as the faster these documents are processed the faster the SAHPRA will be able to generate revenue on new medications as well as tackle the backlog. It should also be noted that the MCC has two training programmes in place for graduates in which graduates are trained to be evaluators. Consultant costs may therefore decrease over the long term because the trainees will become employees of the SAHPRA and some of the current evaluators may be absorbed into the SAHPRA.

Table 1: Rand value of the key cost drivers for the MCC expenditure

Year	2012/13	2013/14	2014/15	2015/16	2016/17
Total Expenditure	75,429,571	90,401,522	100,760,787	114,764,498	28,797,965
COE Expenditure	43,838,517	49,534,325	53,385,770	64,803,985	21,695,750
Consultant and Board Member Expenditure	16,656,270	24,145,572	27,188,879	21,700,052	3,393,446

Figure 1 shows these values as percentages of the total expenditure. Figure 2 shows the average expenditure for the cost drivers from (2012/13 to 2015/16), the average total expenditure on the items as a percentage of total expenditure is 79%.

Figure 1: Expenditure on key cost drivers

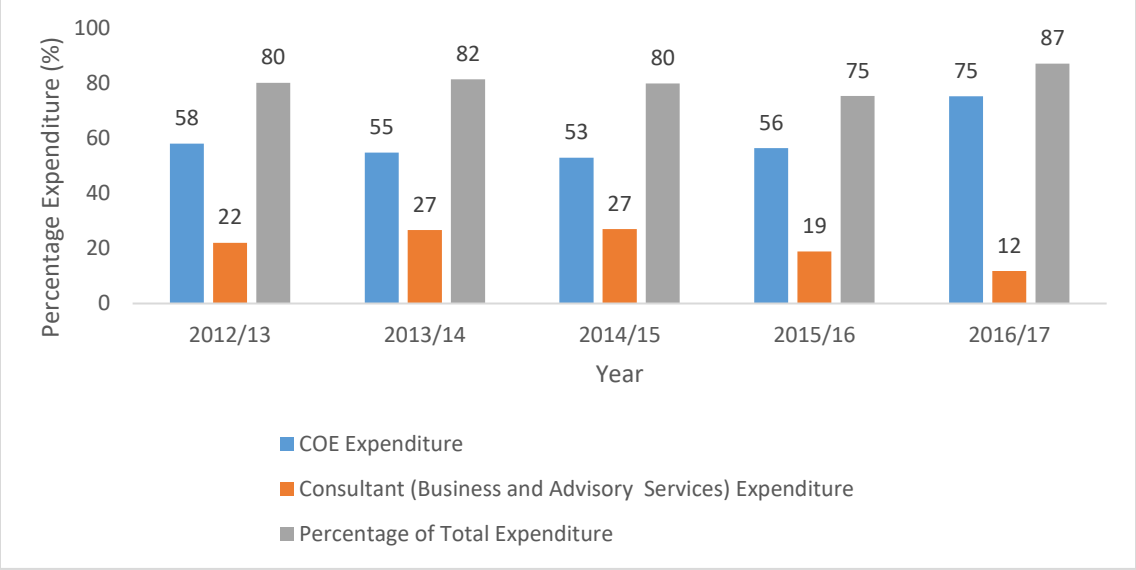
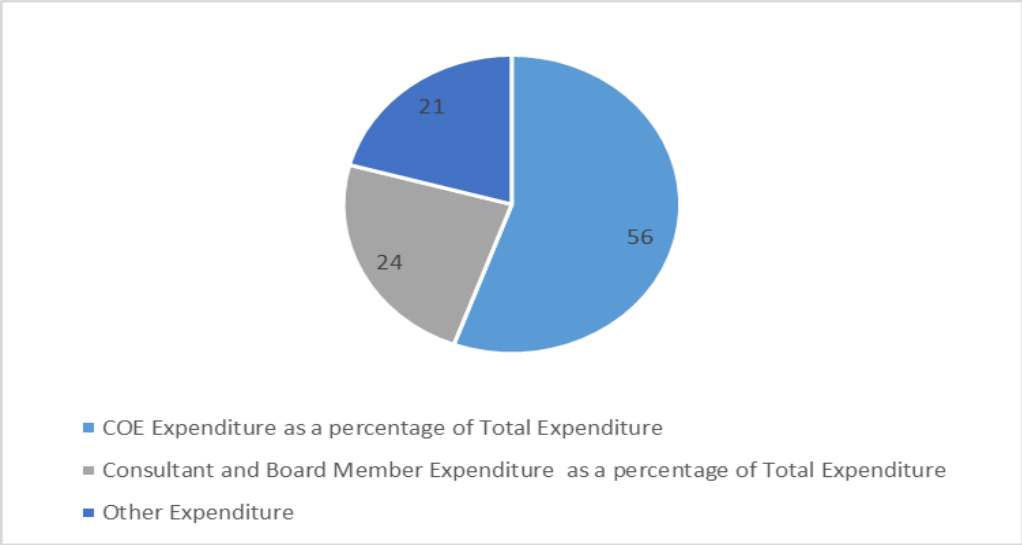


Figure 2: Average Percentage expenditure from 2012/13 to 2015/16



How much has the MCC been receiving and what is the budget short fall?

Table 2 investigates the total budget short fall in the MCC. It can be seen that the MCC has underspent in most years except in 2013/14. The Adjusted budget has been increasing on a yearly basis. It should be noted that the 2016/17 original budget (the amount appropriated to the MCC via the Pharmaceutical Trade and Product Regulation subprogram) has increased by R45 million, from 2015/16 to 2016/17 (from R 94,374,000 to R 139,572,000). This budget has not yet been adjusted and can therefore be expected to increase or decrease in the next few months.

Tables 3 and 4 show that budget pressures do exist in the expenditure of the 2 cost drivers with over expenditure occurring in 3 out 4 financial years (2012/13 to 2015/16), in the consultant and board member expenditure category. . This figure may not be significant but they do give an indication of the pressure experienced by the MCC. Compensation of Employees (COE) seems to be well managed with under expenditure occurring in most instances.

Table 2: Total MCC Budget, expenditure and budget shortfall

	2012/13	2013/14	2014/15	2015/16
Original Budget	74,766,000	89,309,000	96,248,000	94,374,000
Adjusted Budget	77,823,000	89,631,000	117,233,000	115,158,000
Adjusted Amount	3,057,000	(322,000)	20,985,000	20,784,000
Total Expenditure	75,429,571	90,401,522	100,760,787	114,764,498
Total (over) or under Expenditure	2,393,429	(770,522)	16,472,213	393,502

Table 3: Budget pressures experienced in COE expenditure

	2012/13	2013/14	2014/15	2015/16
Original Budget	36,366,000	54,018,000	51,986,000	77,012,000
Adjusted Budget	43,716,000	49,539,000	54,179,000	64,624,000
Adjusted Amount	7,350,000	4,479,000	2,193,000	(12,388,000)
Total Expenditure	43,838,517	49,534,325	53,385,770	64,803,985
Total (over) or under Expenditure	(122,517)	4,675	793,230	(179,985)

Table 4: Budget pressures experienced in consultant and board member expenditure

	2012/13	2013/14	2014/15	2015/16
Original Budget	15,219,000	17,230,000	25,229,000	3,980,000
Adjusted Budget	15,609,000	20,229,000	27,891,000	21,205,000
Adjusted Amount	390,000	2,999,000	2,662,000	17,225,000
Total Expenditure	16,656,270	24,145,572	27,188,879	21,700,052
Total (over) or under Expenditure	(1,047,270)	(3,916,572)	702,121	(495,052)

Costing model:

The costing model (Refer to work book titles “Final Costing model for the SAHPRA” focusses on compensation of SAHPRA employees and the absorption of current MCC employees in year 1 of establishment. Compensation of employees makes up 80% of total expenditure as seen above. The costing section of the model will focus on the cost of the new staff complement of the SAHPRA, using the organogram at DPSA scales 1-15. As mentioned above, the model is engineered on the principles of simplicity and flexibility, which allows for exploration of other possible assumptions. The model therefore allows for the MCC to manipulate it by inserting the total number of new hires as per the salary scale and job title within each year (2017/18 to

2019/20). The MCC or user of the model will be able to examine what the average cost for the new hires would be each year (taking inflation into account) and thereby allowing the user to create a scenario that suits them best in terms of the human resources mix and the available budget for the respective year. The model only takes into account the average salary cost and not the benefits in terms of performance bonuses and leave payments.

Savings: Investing in new staff

One area of savings would be to continue with the training program for Pharmacy students allowing them to be evaluators once the training is completed. These individuals should be absorbed into the SAHPRA as this will mean that there will be less outsourcing to evaluators. This would lower the cost on this expenditure category and it would eventually be phased out once capacity to carry out this work is at an optimum level within SAPHRA. This could not be modelled yet as the costs of training individuals could not be costed in this study.

A second area of savings would not be for the SAHPRA but for the National Treasury. As the SAHPRA becomes more self-sufficient and is able to retain revenue the National Treasury may begin to decrease the amount given to the SAHPRA, the money can go into the national revenue fund and be used for other competing priorities. However as noted earlier this funding should not be phased out completely.

Recommendations moving forward to establish the SAHPRA:

At a later stage the accommodation costs should be added to the model as this will be a major cost driver in the future. The MCC is currently not paying any rent to the Department of Health as it is an organ of this department.

A second area that should be explored in the future should be a revenue generating potential of the SAHPRA. In order to achieve this, assumptions will be formed regarding the volumes of new medications to be registered, the number of current registered applications (and the relevant retention fees amounts) and finally the increase in prices for the registration of these medications in accordance to the rates charged by international MRAs. The MCC also stated that

pharmaceutical companies are willing to pay three times the current price to register medications if the service quality is of an optimal standard (this means shortened turnaround times on applications). The average amount of surplus generated by the MCC over the past few years should be examined here, as well as the amount given to the MCC by the National Treasury. The average annual increases of these figures should be examined an applied to the figure for the next 3 years.

The uptake of new staff should be phased slowly especially during the first year due to the absorption of the current MCC staff and consultants. At a later stage another benefits may be added to the average costs in the model such as performance bonuses (for example setting the performance bonus as a2% of total of the total salary).