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Cannabis Guidelines: Medicines Control Council briefing; Medical Innovation Bill: adoption

Health

15 November 2017

Chairperson: Mr A Mahlalela (ANC) (Acting)

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Meeting Summary

The Portfolio Committee on Health met to hear a briefing by the Medicines Control Council (MCC) on the cannabis guidelines, as well as to consider and vote on the Medical Innovation Bill.

The MCC's report compared the provisions of the Medicines and Related Substances Act with the proposals included in the Medial Innovation Bill. It indicated that the Medicines Act would allow for the use of medical cannabis once permission had been obtained. Permission would have to be requested by a qualified doctor. There were also provisions for the growth, sale and use of cannabis for medical purposes once an application had been processed and approved. The report elaborated on the commercial and industrial uses of cannabis and cannabis by-products, specifically hemp. Cannabis would remain a scheduled substance if used without prior permission. The MCC stressed the need for cooperation across government departments with regard to cannabis, to strengthen capacity, ensure compliance and reap the maximum benefits possible.

The Committee welcomed the report, but had several concerns. Some Members raised questions about compliance and the possible sanctions for non-compliance. Other questions were raised about how easy or difficult it would be to obtain licences to use, grow, transport or sell medical cannabis. There was a feeling that the economic opportunities presented by the Medical Innovation Bill should benefit South Africans, specifically small growers and farming collectives.

The Committee agreed that the essence of the Medical Innovation Bill was captured in the Medicines and Related Substances Act, and that the regulations were sufficient to allow for the use of medical cannabis. The options presented to the Committee were to withdraw the Bill or vote for a motion of non-desirability. The feeling in the Committee was that the hard work which had been put into enabling the use of medical cannabis should not be swept under the carpet. It decided that a report should accompany the motion to show the public how far the Committee had come in discussions around medical cannabis. The vote on the motion of desirability was delayed until the following week's meeting.

Meeting report

Medicines Control Council on Cannabis Guidelines

Mr Griffith Molewa, Law Enforcement Officer: Medicines Control Council (MCC), summarised the aims and objectives of the Medical Innovation Bill of 2014 – the legalising and regulating of cannabinoids for medical and research purposes, and legalising the commercial and industrial use of cannabis to allow for innovation in medical treatment. The MCC had tried to match the Medical Innovation Bill with the existing Medicines and Related Substances Act. He said that the Act had been amended in 2015, and allowed for the sale and use of, as well as clinical trials on, any unregistered substance once permission had been obtained from the MCC. He felt that doctors must be given flexibility to use medical cannabis. Concerns around legalising cannabinoids for medical use were addressed by Section 21 of the Act. Doctors who could handle a specific unregistered medicine could apply to use it. This was strengthened by Section 29 of the Act.

Mr Molewa elaborated on Section 29 of the Medicines and Related Substances Act, commenting that competent doctors could have access to unregistered medicines and give them to patients upon receiving permission to do so. Innovation and legalisation were cornerstones of the Medical Innovation Bill.

Regarding the legalisation of cannabis for industrial and commercial use, he explained that there were different varieties of cannabis. He referred to the Director-General's comment about cannabis by-products. Hemp was a variety of cannabis. He presented the findings of hemp trials which started in 1999 as a collaboration between the Department of Agriculture, Forestry and Fisheries (DAFF), the Department of Health (DOH) and the South African Police Service (SAPS). There was a need to ensure that people knew that hemp and cannabis were not the same, and asked how the Committee might put people's minds at rest.

He addressed whether hemp could be grown in South Africa, saying that it had been proved that different localities or environments had an impact on hemp output. The study showed that the tetrahydrocannabinol (THC) level in hemp was less than 0.1 percent. The Agricultural Research Centre (ARC) had developed two Genetically Modified Organism (GMO) seeds suitable to be grown in South Africa, and these seeds were in the process of being registered and made available to the public. He addressed the guidelines on growing hemp, stating that one option would be to make it an agricultural product. Guidelines were necessary so that people did not confuse hemp and cannabis. One could still get cannabidiol from hemp. If hemp were to be grown for medicinal purposes, the MCC's guideline document, which would look at hemp as a pharmaceutical rather than an agricultural product, must be followed. The MCC must try to address the legalisation of commercial industrial cannabis or hemp.

Mr Molewa focused on the scheduling of cannabis according to the Act. Cannabis was currently a schedule 7 substance, but its medicinal components were in other schedules. There was a lot of confusion around the scheduling of cannabis, since it contained many by-products. Hemp was exempted from schedule 7 as were processed products made from cannabis seeds which contained 0.001 percent or less of THC.

The July MCC meeting had resolved that cannabidiol be rescheduled as a Schedule 4 substance, but that it be classed as a Schedule 7 substance when used for therapeutic purposes. He referred to Section 22A(9)(i) of the Act which prohibited the sale, use, production or possession of any Schedule 7 substance. He felt that this was not a contradiction, given that when cannabinoids were manufactured, they were classed as a Schedule 4 substance but reverted to being a Schedule 7 substance when not used for industrial or commercial purposes. Even though it was a schedule 7 substance, people could access it when needed for medical treatment.

The guidelines for growing cannabis for medicinal and research purposes had been approved by the MCC and were being implemented. They were available on the MCC website and would provide a standardised process for the growing of cannabis. The guidelines required quality products to be grown and for consistency in growing conditions, with minimal differentials in THC levels. They would ensure agricultural best practices were being adhered to, including the types of fertiliser and the amounts of water used. Security requirements would have to be adhered to, to ensure that the product did not fall into the wrong hands. The police must assist with security and providing police clearances to growers or applicants.

Mr Molewa referred to the application forms, which were available on the website and were covered in Section 22C of the Act. He stressed that any person may apply, and that cannabis would still be a scheduled substance, whether it was schedule 4 or schedule 6. He addressed the purpose of Section 22C and made it clear that all people involved – from growth, manufacture, distribution and export of cannabis or cannabis containing medicines– would require a licence.

He said that applications would go through stringent evaluations. Since this was a journey, the MCC would have an open-door policy with stakeholders, both individuals and associations, to address concerns. There would be inspections of growers' sites to ensure compliance and to guard against substandard products. He felt that the Department of Agriculture was best positioned to advise on seeds, and mentioned the establishment of a seed bank to control which seeds could be imported and were acceptable. The DOH and DAFF would need to establish a working group which would be a continuation of the relationship and work these departments had done since the early hemp trials. The MCC did not want to alienate other stakeholders, such as the Department of Science and Technology (DST), which could conduct research. He also felt that there was a need to engage other bodies, such as universities, to improve the process.

Discussion

Ms C Ndaba (ANC) welcomed the presentation for providing a way forward and for drafting guidelines on how to deal with the Medical Innovation Bill. She had previously been concerned that the Bill would create more problems, but supported how the guidelines had been dealt with. All her concerns had been addressed as she did not want people smoking all over the place. She was happy with the formula and guidelines about how the cannabis would be grown. She queried how non-compliance would be dealt with. She felt that there should be penalties rather than leaving the guidelines vague to guard against ill-disciplined people. If the penalties were not in writing, people would take advantage. She requested that the types of cannabis be listed, noting that people like her did not know all of them and needed clarity. The Department of Agriculture should take care of the commercialisation of cannabis. Her concerns had been addressed and the Committee could support the guidelines without any fear.

Ms L James (DA) expressed concern over whether there was the capacity to ensure that cannabis did not fall into the wrong hands. There were huge problems with the SAPS, specifically that there were not enough police officers, and she asked who was going to police the abuse of this opportunity. She was concerned that any person wanting to sell and grow cannabis could do so. There were cannabis growers in Lesotho and Pondoland, where it was used like a cigarette and was difficult to police because of being grown on the mountains. She referred to the Western Cape high court ruling on cannabis, and asked how that was going to be policed. Smokers were getting excited in the townships over the ruling. How would the Committee ensure that cannabis use was protected, including for the growers? How would it differentiate between cannabis grown in Lesotho, in the townships and for medicinal purposes?

Mr N Singh (IFP) acknowledged the contribution of the late Mario Ambrosini of the IFP, thanking him for introducing the bill which had given rise to so much discussion. Tremendous progress had been made. He addressed non-compliance, querying whether sanctions should be enshrined in the act or in the regulations. He expressed his appreciation for how the presentation had been made, by matching the intentions of the bill with current legislation and regulations. He queried whether there would be a need to amend current legislation or whether current legislation would be sufficient to allow for these regulations.

He asked how difficult it would be for farmers to apply for licences to grow cannabis. What was the capacity to deal with these applications and the timeframe for the granting of licences? Had any thought been given to a prescribed fee for growers? He felt that the growing of medical cannabis should be an opportunity for small growers, noting that there were already thousands who operated illegally. Making medical cannabis the preserve of big pharmaceutical companies would defeat the objective of having a developmental state to provide opportunities. He asked if the Department of Agriculture or Department of Health would be responsible for assisting with this process.

Mr Singh said he was glad the Committee agreed on industrial use, but this had taken a long time without much substantive progress. The Committee needed to agree on a timeframe for hemp. Industrial cannabis or hemp production could create jobs and was an opportunity for small growers. He requested clarity on the rescheduling of cannabis from schedule 7 to schedule 6, and asked how this would work practically.

Referring to Section 21, he queried the processing timeframe, mentioning complaints about delays and commented that Mr Ambrosini had received permission for medical cannabis within 24 hours. He asked how difficult it would be for ordinary South Africans and medical practitioners, since it was meant to be quite a process for an application to be considered. Could cannabis grown by someone in South Africa be exported to other countries which allowed for cannabis use? He also queried whether the Bill, as tabled, was now a redundant mechanism to achieve the objectives contained within the Medical Innovation Bill. Had the Bill been overtaken by the regulations?

Dr P Maesela (ANC) said that medicine must be used to preserve life, and this was what the Committee was dealing with. He was happy that there were no more obstacles to making the medicine available. He accepted what the Department had done in removing obstacles and controlling what could be manipulated by those with ulterior motives. Cannabis was not a cure-all medicine, and everyone in the Committee understood what was at stake. He referred to Section 21 of the Medicines and Related Substances Act and said that the terms ‘specific period’ and ‘specific quantities’ were unclear. He asked whether this Act referred to all unregistered medicines.

Mr W Maphanga (ANC) asked whether people who had been previously convicted of growing cannabis would be allowed a licence to grow or sell cannabis. He also queried what criteria would be used in determining whether the application was successful or not.

Ms James asked how and when communities would be educated about the Bill, stressing that these communities must know what it meant.

MCC’s response

Dr Shabir Banoo, Medicines Controls Council, responded that the Members’ questions were the ones the MCC had anticipated. Many of the questions were about sanctions and Mr Molewa, as the head of law enforcement, was the right person to address them. It was important to see how medical cannabis functioned on the ground.

Mr Molewa said that it was heartening to hear the positive feedback,. It was a sign that the MCC were on the right track. He cautioned that it would not be a smooth road ahead. He addressed penalties, saying that the Act had provisions for penalties in certain sections. The licence applications would be done in terms of Section 22C of the act. Anyone who carried out activities without a licence would be in contravention of section 22C, and the penalty would be a fine or jail time, or both. The fine may be small compared to the money made, but it would leave a mark and a criminal record against the offender. Contravening section 21 of the Act would result in similar penalties. Importing scheduled substances without a licence would be dealt with accordingly. He stressed that operations would not be conducted in isolation, and that there would be drug acts dealt with by the police. SARS would deal with tax violations, and offenders would be charged with contraventions of all acts.

Mr Molewa addressed the question about the varieties of cannabis, and said that the MCC was working closely with the

Department of Agriculture on establishing a seed bank to determine which seeds should be used in South Africa.

Regarding community education, the MCC's approach would be to start small and see the outcomes. Where there was a wide interest, it would go to the communities. The Council needed to see how big the problem was and find an appropriate response, and there was the risk of going into the communities unprepared.

Mr Molewa addressed the fee structure, saying that the MCC was busy looking at the whole fee structure for everything dealing with the South African Healthcare Products Regulatory Authority (SAHPRA). The manufacture or extraction of cannabinoids would be dealt with by a different structure.

The issue of exporting cannabis or cannabinoids would depend on whether it was legal in the importing country. Legal trade between consenting parties could not be stopped.

Responding to questions about enforcement, he said that there were many issues which would be looked at when inspections were done, such as competence, land suitability and workers. The MCC would do due diligence to assess whether it should award a licence. For private individuals, it would have to complete a risk assessment, including those with prior convictions. To prevent cannabis from falling into the wrong hands, those transporting cannabis must be able to produce a document specifying what was being transported and from where to where. A similar process was followed for transporting other high schedule medicines, such as morphine. The MCC would have to consult with the police about criminal activity.

Dr Banoo stated that in the early discussions about the Bill, there had been a view that the current provisions allowed for such a framework. The Committee had come a long way since then. Legislative amendments which provided for cultivation had been included. This was an evolving framework and there needed to be local lessons for potential risk factors. He stressed that the Committee did not need to 'reinvent the wheel,' and that many countries had frameworks which allowed for similar processes – promoting research, medical use and realising a standardised product. Key issues had been raised around the efficiencies and effectiveness of the current framework, and part of this would involve building capacity within the regulator to allow for more efficient handling of applications. This was already beginning to be put into place. The involvement of SAHPRA would provide additional efficiency.

He said Mr Maesela's question about Section 21 had been an important one. He felt that there must be provision in law that would allow for access to products which may not have been scrutinised within the country, but had been elsewhere. The way Section 21 was implemented preceded an understanding of what a Section 21 application was about. The MCC had established a framework for the conditional approval of unregistered medicines through its technical Committees. Section 21 was the key provision in the Medicines Act which allowed for wider access, and the possibility of providing access in public health and clinical research. The clinical trial framework was based on Section 21. The MCC remained convinced that it was an ongoing process, and was happy to answer any other questions.

The Chairperson thanked Dr Banoo, and reminded Committee Members that the reason for passing the Bill which had established SAHPRA was to build capacity, and that process was evolving. SAHPRA must be able to process all the applications which needed approval as expeditiously as possible. The matter would not be on a part time basis since there was a fulltime agency to do the work. SAHPRA must address the applications, so it had to evolve and put its own structures and practices into place. Parliament would assess SAHPRA's ability to meet its obligations when it made presentations to Parliament. He felt that the Committee must allow that space to evolve, as the MCC did not have that capacity.

Ms Ndaba expressed concern about the education question, as she felt the answer was not satisfactory. This was an opportunity for South Africans, and she did not want them to be overtaken by outsiders. The government wanted to promote cooperatives as a developmental state. This was why education about the policy was important, specifically for those who were previously convicted for growing cannabis illegally. She also felt that there needed to be stricter penalties, and suggested that on the third offence, people should be stripped of their licenses.

Mr Singh said that his views on section 21 had changed, and that the Committee had to look at how the law could make it easier for people to access medicine. He would take the advice of the Committee and legal advisory team on how to proceed. As far as the Medical Innovations Bill was concerned, all the objections had been catered for. He merely wished for the public to benefit from innovation and alternative forms of medicine and enjoy legal access rather than expensive and unregulated -- and possibly harmful -- backdoor access. This would open a new arena for medical health in South Africa.

The Chairperson indicated that the matter of penalties was addressed in the Medicines Act. The MCC could not determine the penalties, as only the procedure of the court could do so. It was a very broad matter. Regarding the question of public education, there would need to be agreement on what seeds would be used before there could be agreement on public education. What grew somewhere may not grow elsewhere due to soil texture, among other things.

Public education would come in once the list of seeds, and knowledge of what grows where, was established. Medical cannabis should not be left to the Department of Health alone -- the Department of Agriculture and SAPS would be needed to take the discussion forward. He felt that at some point there should be progress and a timeline.

Dr Banoo said that there was a commitment to being proactive. He agreed with Mr Singh that the Medical Innovation Bill had been a journey, and there needed to be a discourse around health care. He reiterated the MCC's commitment to providing feedback and progress. The MCC's primary mandate was to ensure protection of the public and maintain compliance in the context of its international obligations.

Mr Molewa said that whenever a licence or permit was issued, there were always conditions which needed to be adhered to. Mechanisms existed, such as opening a criminal case or sending the drugs back to forensics for destruction. Where a follow-up procedure was not operating, a criminal case would be opened.

He responded to the question around education, reiterating the MCC's open door policy. He believed that by engaging with people, the MCC could see where there was a lack of understanding. By discussing the issues, the MCC and stakeholders would be able to reach some sort of consensus.

The Chairperson thanked the members of the MCC and the Committee, saying that the presentations had been completed, and the Committee would need to decide about the Bill. Either Mr Singh would need to withdraw the Bill in the House, or the Committee would let the Bill go back to the House, taking into consideration all the issues raised. It was up to the Committee to decide which route to take.

Debate on Committee's options

A member of the Parliamentary legal team directed Members of the Committee to the rules. He said that either the Member in charge of the Bill withdraws it, or the Committee goes through a motion of desirability in accordance with the rules of the National Assembly.

The Chairperson felt that the options should be debated, adding that he wanted to see what rule 234 said. He did not want it to seem that the Bill had been put under the carpet after all the work. When the Bill was withdrawn, the Committee would not go back to the House, meaning that it would not have an opportunity to show the public how far it had progressed. His concern with withdrawing was that he feared the Bill would disappear.

Mr Singh agreed with the Chairperson that the Committee had come too far, but this was something for the House to consider. He could not vote against his own Bill in a motion of desirability. The Medical Innovation Bill (MIB) was not desirable in the format of a Bill, and he would look to the Committee for a decision. He felt that the Bill must go to the House, and that all political parties should engage. South Africa needed to know where it was on medical cannabis. He felt that the ruling party would say that it was not desirable. It should go to the House with a full report from the Committee, and he could inform the House that there was no need for the Bill based on the progress in the Committee.

The Chairperson felt that the Bill must go to the House in some form -- it could not just disappear 'under the carpet'.

The representative from the legal team said that there was an option in terms of Rule 286(4)(1), which stated that the Committee must consider a motion of desirability and table the Bill and its report, if the motion of desirability was rejected. Referring to rule 286, sub-section 6, he said that the motion of desirability passes if the adoption of the principles of the Bill and the need for the Bill are accepted. He felt that the only option was for the Committee to go for a motion of desirability, and to table a report to the House as to why the Committee had not found the bill to be desirable.

Ms Ndaba asked the Chairperson to look at other options.

The Chairperson replied that there were only two options. If the Bill was withdrawn, there would be no opportunity to report back. The only option was desirability. He said that a draft had been prepared, and suggested that the Committee go through it and improve on it.

The draft document was circulated to the Members.

The Chairperson said that there were two reports, with page 15 being an annexure. The Committee must agree with and adopt the report. The document indicated when the Bill had been introduced, the sponsor, the briefing from the Department, the briefing from experts, individuals and research institutions, the briefing on guidelines from the MCC, and then what was happening. There was an option which stated that the legislation was not desirable because a mechanism already existed.

He felt that the Committee should include something to show the guidelines and work done which had resulted in the Committee arriving at its conclusion, and that all the achievements had rendered the Bill undesirable. The rules did not provide another way of crafting the outcome, and the motion of desirability had to be in a positive context. This was his view, and he asked for feedback from the Committee.

Dr Maesela said that the objective of the Bill had been met, and the sponsor was satisfied. What the Committee had set out to achieve had been achieved through other means. The agricultural and commercial aspect of cannabis production would be dealt with, but that the Committee had been concerned with its medical uses. Everyone was satisfied, and he asked why the Committee would want to complicate something which had been lauded by everyone and was straight forward.

Ms James said that the Committee would go with the route the Chairperson had suggested. She would discuss the Bill in caucus. She supported the undesirability of the Bill.

The Chairperson said that the decision did not stop Members from caucusing. Members of the Committee should speak with one voice so that it had reached consensus.

Mr Singh agreed, and said that the crafting of the report should focus on the medical aspects. For the record, he was satisfied with the outcome of the meeting. He felt that the report needed to capture the essence of the Bill, stating that the essence was desirable but the methodology was not.

The Chairperson said that the Committee would leave it to the legal team to craft something positive. The Committee would adopt the report at the following meeting with that in mind. The report must talk about desirability and the motion of non-desirability, and must mention the work and achievements of the Committee so that anyone reading it did so in that context. The Committee must find a way of reporting back to Parliament.

The representative from the legal team said he would work to reflect the Committee's view. He asked whether the Committee would hold back, or proceed with the motion.

The Chairperson said that the Committee could conclude the motion if needed. If the report came back, the Committee could look at it and then adopt it. He asked what the motion was.

The representative from the legal team stated that it was not his report, and that the Chairperson should put it to the Committee.

Mr Singh proposed that the legal team should put something in writing. It would take five minutes to meet and decide. Everything that had been said would have to be in the resolution that the Committee would adopt. He felt that 10 to 15 minutes of the next meeting could be set aside, and that the draft could be made available and circulated in time. The Members must read it and then adopt the report at the next meeting.

Ms James agreed with Mr Singh's proposal.

Dr Maesela (ANC) agreed, stating that the Bill was no longer desirable.

The Chairperson said that the problem was about how the rules were crafted, as they did not anticipate such a process. The only option was a motion of desirability. The motion should be preceded by the achievements and work of the Committee which had been informed by the Bill itself. He felt that the report could come to what the rules required the Committee to say, but in a positive way. He asked the Committee if it agreed.

The Committee agreed.

The meeting was adjourned.

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