MEMORANDUM:
A SNAPSHOT OF THE CBD INDUSTRY IN SOUTH AFRICA

SCHINDLERS

attorneys - conveyancers

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INTRODUCTION

1. This memorandum considers whether and how cannabidiol ("CBD") can be sold to the general public.

2. CBD, when intended for therapeutic purposes, is listed as a schedule 4 substance in terms of the Medicines and Related Substances Act 101 of 1965 ("the Medicines Act"), All subsequent references to CBD will be references to CBD when intended for therapeutic purposes.

3. Where advice from the South African Pharmacy Council ("the Pharmacy Council") and/or of the South African Health Products Regulatory Authority ("SAHPRA") is referred to herein, such advice was conveyed to the writers by the head of law enforcement at SAHPRA and the Senior Manager of Legal Services and Professional Conduct at the Pharmacy Council.

CBD AS A MEDICINE

4. CBD is not recognised by our law as a medicine in and of itself, but rather, as an active pharmaceutical ingredient ("API") to be used, in different concentrations, as part of a medicine.

5. At the time of writing, there are no registered medicines in South Africa which contain CBD.

6. While this memorandum does not deal with the registration process in respect of medicines, suffice it to say that, on the advice of SAHPRA, this process takes up to 5(Five) years.

7. Although the relevant legislation would appear to suggest otherwise, the Pharmacy Council and SAHPRA confirm that APIs may not be sold to the general public.

8. Furthermore, section 14 of the Medicines Act, subject to sections 21 and 22A thereof, provides that no person shall sell any unregistered medicine if such medicine or class of medicine is required to be registered by SAHPRA.

9. We have been advised by SAHPRA that the "pain management" class of substances, which includes CBD, has been called up for registration.

10. Accordingly, CBD-containing medicine may be sold by anyone unless same is registered with SAHPRA, a process which, according to SAHPRA, takes up to 5 (Five) years.

WHO MAY SELL CBD?

11. Section 22A(5) of the Medicines Act essentially permits either pharmacists or medical practitioners[1], who are licenced to do so under section 22C(1)(a) of the Medicines Act, to sell substances belonging to schedules 2, 3, 4, 5 and 6 of the Medicines Act for consumption by human beings.

12. Accordingly, if a CBD-containing medicine were to be successfully registered, medical practitioners would only need to obtain a licence in terms of 22C(1)(a) of the Medicines Act in order to stock and dispense such medicine.

13. However, the idea of medical practitioners dispensing CBD-containing medicines does little for the vision of a CBD industry in which paying customers would be able to walk into a premises and choose from a wide variety CBD-containing products.

14. As will be explained below, so long as CBD remains categorised between schedules 2 and 8, the only premises which may legally stock and sell CBD-containing medicines are licenced pharmacies.

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[1] *Section 1 of the Medicines Act defines a medical practitioner as "a person registered as such under the Health Professions Act, 1974, and includes an intern regi*stered under that Act".

15. In the interim, medical practitioners are able to apply on behalf of their patients, in terms of section 21 of the Medicines Act, to import and sell an unregistered medicine, which is registered in a foreign jurisdiction which is recognised for this purpose by SAHPRA.

16. This application therefore allows medical practitioners to, if successful, supply their patients which CBD-containing medicine. However, this application, if successful only allows a single patient access to a limited amount of an unregistered medicines for a limited time. A new application must also be made for each induvial patient. Furthermore, in order to be successful in the application, the medical practitioner must satisfy SAHPRA that no locally registered medicines are capable of adequately treating the patient in question, i.e. the unregistered medicine must be a necessity and not merely a preference.

WHO MAY PURCHASE CBD?

17. Section 22A(16) of the Medicines Act provides that any person may be in possession of a schedule 4 substance if he or she is also in possession of a prescription issued by an authorised prescriber.[2]

18. Accordingly, CBD-containing medicines may only be sold to people who are in possession of an appropriate prescription or to people who are the subjects of successful section 21 applications as explained above.

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[2] *Section 22A(17)(a) of the Medicines Act defines an authorised prescriber as "a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974".*

THE NECESSITY OF PHARMACISTS

19. Subject to what has been set out above, section 13(1) of the Pharmacy Act provides that:

> *"no person shall be entitled to provide the services which form part of the services specially pertaining to the scope of practice of a pharmacist or assist therewith, unless he or she is duly registered in one of the categories prescribed in terms of this Act".*

20. In this regard, regulations 3 and 4 of the Regulations Relating to the Practice of Pharmacy ("the Practice Regulations") set out the acts which shall be regarded as "specially pertaining to the profession of a pharmacist" or, in other words, acts which can only be carried out by pharmacists.

21. Upon even a perfunctory reading of these regulations, it becomes apparent that almost all conceivable business practices relating to scheduled substances fall within the acts which shall be regarded as specially or generally pertaining to the profession of a pharmacist.

22. Therefore, in accordance with section 13(1), in order to carry out any of the acts or services alluded to in paragraph 20 above, a person must be duly registered in one of the categories prescribed in terms of the Pharmacy Act.

23. However, this requirement is somewhat vague, in that the Pharmacy Act, through its numerous additional regulations, prescribes many categories of persons which clearly cannot and are not meant to carry out certain acts, specially or generally pertaining to the profession of a pharmacist. Only categories of persons who, in addition to being so categorized, are also registered pharmacists may carry out the acts specially and generally pertaining to the profession of a pharmacist. Categories of persons who are not also registered pharmacists may only, in certain instances, assist pharmacists in carrying out such acts.

24. It follows that a pharmacist must, by law, be at the centre of any business plan which entails the sale of a scheduled substance such as CBD. This begs the question of where pharmacists may provide the services and/or carry out the acts required of them in order to execute such business plans.

LICENSING OF PHARMACIES

25. Unsurprisingly, the only type of premises capable of being adequately licenced for the purpose of lawfully facilitating the acts specially and generally pertaining to the profession of a pharmacist, is a pharmacy.

26. In this regard, regulation 99 of the Regulations Relating to the Registration of Persons and the Maintenance of Registers ("the Registration Regulations") provide for five different categories of pharmacy, namely, manufacturing, wholesale, community, institutional and consultant pharmacies.

27. However, community and institutional pharmacies are the only types of pharmacies at which a pharmacist may dispense or sell medicines to the general public.

28. The essential difference between community and institutional pharmacies is their location. Community pharmacies can only be established in areas from which they satisfy a collective need expressed by a particular community for access to pharmaceutical products. Institutional pharmacies, however, can only be established in either public or private health facilities such hospitals, clinics, or community healthcare centres.

29. Manufacturing pharmacies on the other hand may handle APIs, manufacture medicines and apply for the registration of medicines. It follows that an application for the registration of a CBD-containing medicine would eventually emanate from a manufacturing pharmacy.

30. Wholesale pharmacies are tasked with the distribution of medicines exclusively to institutional and community pharmacies.

31. Consultant pharmacies advise people regarding the effectiveness and safety of medicines, treatment and therapies and engage in pharmaceutical research and development.

32. With respect to who may own any kind of pharmacy, readers are advised to consult sections 22(1) and 22A of the Pharmacy Act read with the Regulations Relating to the Ownership and Licensing of Pharmacies ("the Licensing Regulations").

REGISTRATION OF PHARMACY

33. Once a pharmacy has been licenced, it must then be registered by the Pharmacy Council. Naturally, a pharmacy will be registered as a company before such time as it is granted.

34. With specific regard to the structure of a company which obtains a licence to carry on the business of a pharmacy, regulations 47 and 48 of the Registration Regulations provide that a pharmacist must be appointed, designated and registered as managing director of such company, that a natural person[3] must be appointed and registered to act as nominee[4] in respect such company and that the company itself must also be registered as a pharmacy.

35. In particular, regulation 48 also provides a that company, which intends to carry on the business of a pharmacy, must submit a number of specified documents to the Registrar of the Pharmacy Council ("the Registrar").

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[3] *Such person must be a pharmacist who resides in the Republic of South Africa and a director of the company.*

[4] *The natural person appointed and registered as such by a company or a close corporation entitled to carry on the business of a pharmacist in terms of the Act and who shall be responsible for the duties as prescribed in regulation 24 of the Regulations Relating to the Practice of Pharmacy.*

36. Regulation 50 of the Registration Regulations further provides that every company which complies with the Registration Regulations and sections 22 and 22A of the Pharmacy Act must be registered as a company entitled to carry on the business of a pharmacy and issued with a registration certificate by the Registrar, indicating the category of pharmacy in which it may carry on such business.

37. Lastly, regulations 67 to 71 of the Registration Regulations must be adhered to by all pharmacies regardless of their category.

IMPORTING CBD

38. Notwithstanding the fact that the activity of importing scheduled substances is quoted in regulation 3 of the Practice Regulations specially pertaining to the profession of a pharmacist, it does not fall within the scope of the activities which may be conducted by any category of pharmacy defined in the Licensing Regulations. In fact, the issue of importing scheduled substances, such as CBD, is not dealt with anywhere in the Pharmacy Act.

39. However, as stated in paragraph 3 above, section 22A(5) of the Medicines Act allows for a defined list of persons, pharmacists among them, to sell schedule 4 substances. In the Medicines Act the word "sell" "means sell by wholesale or retail and includes import …" [emphasis added].

40. The importation of scheduled substances is specifically dealt with in section 22C(1)(b) of the Medicines Act which provides that the South African Health Products Regulatory Authority ("SAHPRA") may, on application, issue licences which allow for specified groups

41. While it is apparent that pharmacists are not specifically mentioned in section 22C(1)(b), the Medicines Act must be interpreted in such a way as to breathe life into their right to import schedule 4 substances, such as CBD, as provided for in section 22A(5) thereof. However, section 22C(1)(b) does make mention of distributors. Distribution of scheduled substances appears to fall within the scope of practice of pharmacists. Accordingly, pharmacists can certainly be considered as distributors for the purpose of obtaining a licence in terms of section 22C(1)(b). In any event, the Pharmacy Council has confirmed that pharmacists require a s22C Licence in order to import scheduled substances irrespective of the type of pharmacy in which they operate.

CONCLUSION

42. It is apparent that any potential market for CBD and CBD-containing medicines is extremely limited by South Africa's laws as they presently exist.

43. CBD-containing medicines may not be sold to the general public unless they are registered (a process which can take up to 5 years) and the public may not purchase such medicines unless they are possessed of an appropriate prescription.

44. In the interim, the section 21 application explained in paragraphs 15 and 16 above is available to patients who are unable to obtain adequate relief from any locally registered medicines.

45. However, since the Constitutional Court has, in the case of Minister of Justice and Constitutional Development and Others v Prince; National Director of Public Prosecutions and Others v Rubin; National Director of Public Prosecutions and Others v Acton and Others [2018] ZACC 30, mandated Parliament to amended South Africa's laws in respect of cannabis, the writers are hopeful that Parliament ventures beyond the confines of the Constitutional Court's declarations of invalidity and endeavours to remove the significant barriers faced by the South African CBD and cannabis industries.

46. Schindlers avails itself to assist the reader through the various alternative legal requirements/processes/applications, as detailed above.