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LOCKING-DOWN OUR CANNABIS LAWS

1 On **22 May 2020**, the Minister of Health, by way of Government Notice R.586,[1] ("the Amendment") amended, as it was empowered to do, schedules 4, 6 and 7 of the Medicines and Related Substances Control Act 101 of 1965 ("the Medicines Act").

2 This memorandum explores the consequences of the Amendment, schedule by schedule, and inasmuch as these revised schedules are applicable to the South African cannabis industry and cannabis law as a whole.

3 However, this does not constitute blanket legal advice, nor a complete exposition of the effects of the Amendment, and context-specific legal advice ought to be obtained by each person who is desirous of engaging in any activities which are affected by the Amendment.

SCHEDULE 4

4 The Amendment adds that substances in schedule 4 of the Medicines Act, along with all preparations and mixtures thereof, are excluded from schedule 4 when specifically (i) packed, (ii) labelled, (iii)sold **and** (iv) used for:

4.1 industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

4.2 analytical laboratory purposes.

5 In other words, schedule 4 substances that meet the aforementioned requirements are exempt from the scheduling of the Medicines Act in its entirety and are, therefore, not regulated by the Medicines Act, nor subject to any licences or permits (issued in terms of the Medicines Act).

[1] **https://archive.opengazettes.org.za/archive/ZA/2020/government-gazette-ZA-vol-659-no-43347-dated-2020-05-22.pdf**

6 Analytical laboratory purposes aside, the requirement that consumer items or products must have no pharmacological action or medicinal purpose ought to be reemphasised.

7 In the context of cannabidiol ("CBD") this means that the exemption set out in paragraph 5 above is not applicable where CBD is used to manufacture or compound consumer items or products that are intended to be ingested or applied to the body as a cosmetic, because CBD, being an active pharmaceutical ingredient ("API") is touted as having both pharmacological actions and medicinal purposes. However, where a material that contains CBD is used in order to produce other consumer items or products such as hemp-based clothing or concrete, the CBD component of that material is exempt from the scheduling of the Medicines Act.

8 The Amendment has also changed the definition of CBD such that all preparations/mixtures containing CBD are considered to be schedule 4 substances, unless the preparation/mixture in question is contained in:

8.1 complimentary medicines containing no more than 600mg (30 daily doses) of CBD per sales pack and providing a maximum daily dose of 20mg and making a general health enhancment, health maintenance or relief of minor symptoms claim ("Option 1"); **or**

8.2 processed products made from cannabis raw plat material intended for ingestion and containing 0,0075% or less of CBD where only the naturally-occurring quantity of cannabinoids found in the source material are contained in the product ("Option 2"), in which case the preparation/mixture will be considered to be a schedule 0 substance ("schedule 0 CBD products"),

in which case the preparations/mixtures will be considered to be schedule 0 substances ("schedule 0 CBD products").

9 While section 22A(3) of the Medicines Act provides that any schedule 0 substance may be sold in an open shop, schedule 0 is not necessarily a free pass.

10 Schedule 0 substances are still scheduled substances. Therefore, one would also need a licence in terms section 22C(1)(b) of the Medicines Act in order to (i) manufacture, (ii) import, (iii) export, (iv) wholesale or (v) distribute schedule 0 CBD products ("s22C Licence").

11 As alluded to in paragraphs 8.1 and 8.2 above, one has two options should one desire to render a CBD product a schedule 0 substance. In Schindlers' experience, the cannabis community views Option 2 as a waste of time, given the arbitrarily low percentage of CBD that it requires. However, unlike the Option 1, Option 2 does not require that the CBD product in question be a complimentary medicine.

12 On the other hand, Option 1 schedule 0 CBD products are, by definition, complimentary medicines. Although Option 1 requires preparations/mixtures of CBD to be contained in complimentary medicines, it is submitted that, because CBD originates from a plant and because Option 1 requires that schedule 0 CBD products must make a general health enhancement, health maintenance or relief of minor symptoms claim, Option 1 schedule 0 CBD products meet the current definition of a complimentary medicine (see paragraph 15.2 below) and would, therefore, have to adhere to the laws in respect of complimentary medicines irrespective of whether or not the phrase "complimentary medicine" was actually included in Option 1 or not.

13 Before **15 November 2013**, complementary medicines were undefined and unregulated.

14 On **15 November 2013**, and by way of Government Notice R.870 ("Notice 1"): [2]

14.1 complementary medicines were first defined and categorised as category D medicines;

14.2 category D medicines were further subdivided into a number of pharmacological classifications; and

14.3 it was decided that category D medicines (hereinafter referred to as "complementary medicines") would be subject to registration as medicines and that applicants for registration would be required to apply before different dates depending on the pharmaco logical classification of the complementary medicine being registered.

15 On **25 August 2017**, and by way of Government Notice 859:[3]

15.1 the general regulations in respect of the Medicines Act, as we know them today, were established;

15.2 "complementary medicine" was redefined to mean any substance or mixture of substances that-[4]

(a) "originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Authority;

(b) is used or purporting to be suitable for use or manufactured or sold for use -

(i) in maintaining, complementing or assisting the physical or mental state; or

(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and

(c) is used -

(i) as a health supplement; or

(ii) in accordance with those disciplines as determined by the Authority;"

15.3 the pharmacological classifications in respect of complementary medicines were redefined; and

15.4 the previous timeline set out in Notice 1 for the registration of complementary medicines was deleted, thus causing the position to revert to its default, i.e. that complementary medicines would have to be registered in response to "call-up" notices issued by SAHPRA in terms of section 14(2) of the Medicines Act.

2 https://archive.opengazettes.org.za/archive/ZA/2013/government-gazette-ZA-vol-581-no-37032-dated-2013-11-15.pdf
3 https://archive.opengazettes.org.za/archive/ZA/2017/government-gazette-ZA-vol-626-no-41064-dated-2017-08-25.pdf at pages 47 to 128
4 We note that this definition is presently being challenged by the Alliance of Natural Health Products (South Africa) under case number 11203/18

16 During **August 2019**, SAHPRA then released a publication which was to serve as a roadmap in respect of, among other things, the registration of complementary medicines. This publication provided:.

16.1 a link to SAHPRA's electronic complementary medicine platform (www.sahpracm.org.za) at which all information pertaining to the registration of complimentary medicines (inclusive of application forms) may be found;

16.2 useful guidelines regarding the registration of complementary medicines;

16.3 useful guidelines regarding the regulatory framework that applies to complementary medicines;

16.4 that all applications for the registration of complimentary medicines already submitted to SAHPRA would continue to be processed by SAHPRA without further action being required;

16.5 a proposal that the call-up notices mentioned in paragraph 15.4 above would be rolled out in February/March 2020; and

16.6 that a transitional period of 6 months would be afforded to manufacturers, importers, exporters, wholesalers and distributors of complementary medicines, prior to the publication of a new call-up notice, during which these stakeholders may apply for a s22C Licence. After the publication of the call-up notice in question, any new manufacturers, importers, exporters, wholesalers or distributors of a complementary medicine must hold a s22C Licence prior to manufacturing, importing, exporting, wholesaling or distributing such medicine.

17 From paragraph 16.6 above, it would appear that one would only be required to obtain a s22C Licence once the relevant complementary medicine is called up for registration. However, it is submitted that, where the complimentary medicine in question is also a scheduled substance, as is the case with schedule 0 CBD products, a s22C Licence is required from inception.

18 It is reemphasised that a s22C Licence is only required when one seeks to (i) manufacture, (ii) import, (iii) export, (iv) wholesale or (v) distribute schedule 0 CBD products, since section 22A(3) of the Medicines Act provides that any schedule 0 substance may be sold in an open shop.

19 Once call-up notices in respect of complimentary medicines have been issued in terms of section 14(2) of the Medicines Act, section 14(3)(a) further provides that, if a complementary medicine was available for sale in South Africa immediately prior to being called up in terms of section 14(2), it may continue to be sold if an application for the registration of such medicine is submitted within six months of the call up.

[5] **http://www.sahpra.org.za/wp-content/uploads/2019/09/7.02_Roadmap_for_CMs_Aug19_v2-1.pdf**

20 Furthermore, complimentary medicines must also specifically adhere to the requirements of section 20 and regulations 10, 11, 12 and 42 of the Medicines Act, as well as any other relevant provisions of the Medicines Act and its regulations.

21 **In summary:**

21.1 a preparation/mixture which adheres to the requirements set out in Options 1 or 2 (paragraphs 8.1 and 8.2 above) is a schedule 0 substance;

21.2 in order to (i) manufacture, (ii) import, (iii) export, (iv) wholesale or (v) distribute a scheduled substance, one must apply for and obtain a s22C Licence;

21.3 section 22A(3) of the Medicines Act provides that any schedule 0 substance may be sold in an open shop;

21.4 a preparation/mixture which adheres to the requirements set out in Option 1 (paragraph 8.1 above) is also a complimentary medicine;

21.5 complimentary medicines must be registered when called up in terms of a call-up notice issued by SAHPRA;

21.6 complimentary medicines must also specifically adhere to the requirements of section 20 and regulations 10, 11, 12 and 42 of the Medicines Act, as well as any other relevant provisions of the Medicines Act and its regulations; and

21.7 section 14(3)(a) further provides that, if a complementary medicine was available for sale in South Africa immediately prior to being called up in terms of section 14(2), it may continue to be sold if an application for the registration of such medicine is submitted within six months of the call up.

22 It ought to be noted, further, that if CBD products are registered under schedule 4, thereby circumventing the limitations imposed by Options 1 and 2, they can only be sold by the persons set out in section s22A(5) of the Medicines Act.

23 Section 22A(5) of the Medicines Act provides, among other things, that all substances in schedules 4 and 6 of can only be sold by:

23.1 pharmacists and, subject to certain conditions, pharmacist interns and pharmacist's assistants upon presentation of a written prescription by an authorised prescriber;

23.2 a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess schedule 4 and 6 substances;

23.3 medical practitioners or dentists who may prescribe schedule 4 and 6 substances or who may compound or dispense schedule 4 and 6 substances only if he or she is the holder of a licence as contemplated in section 22(C)(1)(a) of the Medicines Act; and

23.4 a practitioner, a nurse or a person who is registered under the Health Professions Act 56 of 1974, other than a medical practitioner or dentist, who may (i) prescribe only the substances identified in schedules 4 and 6 for that purpose or (ii) compound and dispense schedule 4 and 6 substances only if he or she is the holder of a licence as contemplated in section 22(C)(1)(a) of the Medicines Act.

24 The Amendment further specifies that (i) paramedics (ii) emergency care practitioners, (iii) dental therapists (iv) optometrists and (v) podiatrists may prescribe a set list of schedule 4 substances, none of which include CBD or tetrahydrocannabinol ("THC").

25 Albeit that the Amendment may frustrate many of those already trading in CBD and CBD products, it remains clear that the previous (transitional) regime, i.e. under Government Gazette Notice R.756 of 23 May 2019, created legal uncertainty, in that:

25.1 it purported to exclude certain CBD preparations from being subject to the operation of the Medicines Act; and yet

25.2 SAHPRA then adopted the (legally nonsensical) position that traders in these preparations required licenses in terms of the Medicines Act.

26 The law around what one can and cannot do, and under what circumstances, has now been refined. It may not be the answer that people were seeking, but it is a clearer answer, nonetheless. This increased clarity can only benefit the cannabis industry and those who wish to participate in it.

SCHEDULE 6

27 The Amendment has, among other things, deleted dronabinol from schedule 6 of the Medicines Act and replaced it with THC, along with all preparations and mixtures thereof, except:

27.1 in raw plant material and processed products manufactured from such material, intended for industrial purposes and not for human or animal ingestion, containing 0,2% or less of THC ("Exemption 1");

27.2 processed products made from cannabis containing 0,001% or less of THC ("Exemption 2"); or

27.3 when raw plant material is cultivated, possessed, and consumed by an adult, in private for personal consumption ("Exemption 3").

28 The inclusion of THC in schedule 6 now means that medicines containing THC may be prescribed and sold in accordance with section 22A(5) of the Medicines Act, once they have been registered.

29 Exemptions 1 to 3 exempt THC from the scheduling of the Medicines Act in its entirety, with the effect that THC, which meets the requirements set out in Exemptions 1 to 3, is not regulated by the Medicines Act, nor subject to any licences or permits (issued in terms of the Medicines Act).

30 Exemption 1, much like in the case of CBD, means that, where 0.2% or less of THC is contained in raw plant material and processed products manufactured from such material which are intended for industrial purposes and not for human or animal ingestion, the THC components of that raw plant material and those processed products are exempt from the scheduling of the Medicines Act.

31 Exemption 2 means that where 0.001% or less of THC is contained in processed products (which phrase is board enough to include products intended for human or animal ingestion) the THC components of those processed products are exempt from the scheduling of the Medicines Act.

32 Exemption 3 means that, where THC is contained in raw plant material which is cultivated, possessed, and consumed by an adult, in private for personal consumption, the THC component of that raw plant material is exempt from the scheduling of the Medicines Act.

33 Exemption 3 is a clear attempt to legislate in accordance with the order handed down in 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 ("the Judgment").[6]

34 However, what the Amendment fails to appreciate is that the raw plant material of cannabis also contains CBD and other cannabinoids. The Amendment only exempts the private consumption of THC.

35 In any event, the Judgment:

35.1 is clear in its directive that adults are allowed to personally cultivate, possess and consume the whole of the cannabis plant in private; and

35.2 takes precedence over the Amendment.

SCHEDULE 7

36 "Cannabis, the whole plant, or any part thereof …" has been removed from schedule 7 of the Medicines Act.

37 For the sake of clarity, schedule 7 of the Medicines Act no longer contains any reference whatsoever to cannabis or cannabinoids.

38 The combined effect of the removal of cannabis from schedule 7 and the observations set out in paragraphs 4 to 7 and 30 above, is to remove cannabis seeds and industrial hemp from the ambit of the Medicines Act (to the extent that same contain CBD and/or 0.2% or less of THC and are not intended to be ingested or to be applied to the body as a cosmetic).

39 In other words, the cultivation, processing and sale of industrial hemp and cannabis seeds, which meet the aforementioned description, requires no licences or permits (issued in terms of the Medicines Act).

6 **http://www.saflii.org.za/za/cases/ZACC/2018/30.pdf**

40 However, the Drugs and Trafficking Act 140 of 1992 ("the Drugs Act") post the Judgment:

40.1 defines a drug as "any dependence-producing substance, any dangerous dependence-producing substance or any undesirable dependence-producing substance";

40.2 classifies "cannibis, the whole plant or any portion thereof" [sic] and THC as undesirable dependence producing substances;

40.3 defines "deal in" as performing any act in connection with the transhipment, importation, cultivation (other than the cultivation of cannabis by an adult in a private place for his or her personal consumption in private), collection, manufacture, supply, prescription, administration, sale, transmission or exportation of a drug; and

40.4 provides that no person shall deal in any undesirable dependence producing substances unless he or she is a person contemplated in or licenced in terms of Medicines Act.

41 Because industrial hemp and cannabis seeds (which meet the requirements set out in paragraph 42 above) are excluded from the ambit of the Medicines Act, the Drugs Act makes it illegal to deal in same.

CONCLUSION

42 The amendments under discussion provide some insight into the direction that government intends to move, but only partially. In order for the full picture to be completed, we need still to see what government intends to do:

42.1 in respect of standalone legislation addressing the Judgment;

42.2 regarding whether or not to allow for a formalised and regulated "recreational" cannabis industry;

42.3 how the Drugs Act will be amended to give effect to everything intended; and

42.4 vitally, in respect of inviting public participation and comment on whatever draft pieces of legislation, or amendments, follow upon this memorandum.

BUSINESS DETAILS

- Contact Schindlers Attorneys for all cannabis-related assistance **cannabis@schindlers.co.za**

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