Comments from The Swedish Medical Products Agency on Draft Commission Services’ non-paper, version 01/03/2022

Introduction and conclusions

The Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs has written a draft non-paper with the purpose to serve as a basis for discussion between the Commission and the members of The Working Group on Cosmetic Products. The aim is to provide preliminary views and further explanations on the implications of the Court of Justice, CJEU, judgment case C-663/18 on the cosmetics sector.

As a part of The Working Group on Cosmetic Products, the department of Cosmetics, Medicinal Products and Narcotics at the Swedish Medical Products Agency has been given the opportunity to comment on the draft non-paper. We thank the Commission for your efforts in providing guidance to the Member States in this complicated matter. However, we would like to highlight our hesitations regarding some of the conclusions that are being made in the non-paper.

- A preparation containing tetrahydrocannabinol, THC, is considered a narcotic in Sweden regardless the origin of the THC or quantity of the THC in the preparation. Possession of such preparation may constitute a criminal offence. The conclusion made in section 3.2 and 3.5 in the non-paper, that cannabis-derived products containing THC should not qualify as ‘drugs’ if they are produced from parts of the cannabis plant which are not considered as a ‘drug’ by the Single Convention, is not consistent to Swedish law.

- Our opinion is that the chemical substance CBD is not a prohibited substance in cosmetic products and that it is therefore allowed, provided that the cosmetic product is safe for human health as required by article 3 of the CPR. We agree that the same conclusions can apply to other cannabinoids that have no psychotropic effects. However, we disagree with the conclusions regarding the cannabinoid THC and regarding the use of parts of the cannabis plant that are considered narcotics in the Single Convention.

- Our understanding is that a cosmetic product containing THC is a preparation under the Convention on Psychotropic Substances and therefore considered a ‘drug’. Since possession of a preparation containing THC, regardless concentration, is a criminal offence according to Swedish law, we do not support a statement that THC in cosmetic products should be accepted.

- There is a risk in stating that some ingredients are allowed in cosmetic products when they in fact may not be so in all Member States. This can for instance result in
companies believing their products are lawful when in fact they could be at risk of committing a criminal offence in Sweden.

The Swedish legislation on narcotics

According to the Penal Law on Narcotics (SFS 1968:64), narcotics are defined as medicines or goods dangerous to health, that have addictive characteristics or euphoretic effects, or goods that easily can be transformed to such goods, and because of these characteristics are pointed out by the Swedish government as narcotics, as well as substances that are subject to regulation in a convention that Sweden has ratified. Sweden has ratified both the Single Convention on Narcotic Drugs of 1961, hereafter the Single Convention, and the Convention on Psychotropic Substances of 1971, hereafter the Convention on Psychotropic Substances. The use and possession of illicit drugs are criminal offences under the Penal Law on Narcotics.

Regarding cannabis, all parts above ground (except the seeds), from which the resin has not been extracted, is regarded as narcotics in Sweden regardless under which name it is presented, except if the variety of cannabis is one that can qualify the grower financial aid according to EU regulations and the cannabis is cultivated after an application for such financial aid has been submitted in accordance with the EU regulation.

In a precedent judgment by the Swedish Supreme Court (NJA 2019 s. 531), a CBD oil that contained THC was considered to constitute a preparation as defined by the Convention on Psychotropic Substances and therefore a narcotic, even though the THC in the CBD oil derived from a variety of cannabis that is exempted from the definition of cannabis in the Swedish legislation. The amount of THC in the oil was not possible to determine. Consequently, a preparation containing THC is considered a narcotic in Sweden regardless the origin of the THC or quantity of the THC in the preparation. Possession of such preparation may be considered a criminal offence. Therefore, the conclusion made in section 3.2 and 3.5 of the non-paper, that cannabis-derived products containing THC should not qualify as ‘drugs’ if they are produced from parts of the cannabis plant which are not considered as a ‘drug’ by the Single Convention, is not consistent to Swedish law.

Case C-663/18

In the case C-663/18 the CJEU ruled that articles 34 and 36 TFEU must be interpreted as precluding national legislation which prohibits the marketing of cannabidiol (CBD) lawfully produced in another Member State when it is extracted from the Cannabis Sativa plant in its entirety and not solely from its fibre and seeds, unless that legislation is appropriate for securing the attainment of the objective of protecting public health and does not go beyond what is necessary for that purpose.
CBD is an organic chemical possible to derive from the Cannabis plant with different methods. Products with CBD contain more ingredients than just CBD, for example an oil solution and other chemicals. We believe that it is a reasonable conclusion that the judgment in the case is applicable only to CBD as an organic chemical substance rather than the CBD product at stake in the case (CBD liquid with other ingredients and other organic chemicals than CBD, such as small amounts THC). For example, in paragraph 63 and 64 in the judgment the Court states, inter alia, that it is necessary to determine whether the CBD at issue in the main proceedings constitutes a narcotic drug within the case-law presented and that it in that regard should be noted that *that substance* (italics added) is not covered by the Convention on Psychotropic Substances. Therefore, we do not agree with the conclusion that one of the elements explaining why the CJEU refused to pursue a literal interpretation of the Single Convention was the fact that the CBD in the case was produced from cannabis containing under 0.2 % THC. Rather, we argue that the reason for this was the fact that the CBD at issue in the main proceedings had no psychotropic effect or harmful effect on human health on the basis of available scientific data (paragraph 72), a statement that is not applicable on THC. Consistently, we also question the conclusions that are being made in the non-paper regarding THC based on this judgment.

**Cannabinoids in cosmetics**

**CBD and other non-psychoactive cannabinoids**

The CJEU ruled in the case C-633/18 that CBD should not be included under the definition of ‘drugs’ in the Single Convention even in cases where the CBD is extracted from parts of the cannabis plant that are under the control of that convention. Accordingly, the CBD at issue in the main proceedings should not be considered as a drug within the meaning of the Single Convention. Furthermore, CBD is not subject to control by the Convention on Psychotropic Substances. The chemical substance CBD is therefore not a prohibited substance in cosmetic products and should be allowed provided that the cosmetic product is safe for human health as required by article 3 of the CPR. We also agree that the same conclusions can apply to other cannabinoids that have no psychotropic effects. However, we disagree with the conclusions regarding the cannabinoid THC and the use of parts of the cannabis plant that are considered narcotics in the Single Convention.

**THC**

As stated in the non-paper, cosmetic products shall not contain any of the prohibited substances listed in the Annex II of Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009, hereafter CPR, (article 14(1)). Entry 306 of Annex II to CPR refers to “Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on narcotic drugs of 1961”. A cannabis extract that contains THC is subject to control in the Single Convention. Article 17 of CPR states, inter alia, that the non-intended presence of a small quantity of a prohibited substance shall be permitted provided that such presence is in conformity with Article 3 regarding safety of cosmetic products. Our opinion is, on the contrary to the statement made in the non-paper, that a cosmetic product containing ingredients that are narcotics cannot be considered safe for human health and therefore does not fulfil the criteria in article 3 of CPR.
The Convention on Psychotropic Substances also put preparations containing THC under control. In that convention, ‘preparation’ means i) any solution or mixture, in whatever physical state, containing one or more psychotropic substances, or ii) one or more psychotropic substances in dosage form.¹ We suggest that a cosmetic product typically consists of different ingredients and therefore, typically, is considered a ‘mixture’. Furthermore, the definition of a ‘cosmetic product’ in CPR is ‘any substance or mixture intended to be placed in contact with the external parts of the human body...’ and ‘mixture’ in CPR means ‘a mixture or solution composed of two or more substances’. Therefore, the statement that milk and other animal products are not to be considered as preparations within the meaning of the Convention on Psychotropic Substances seems to be of little relevance. Our conclusion is that a cosmetic product containing THC is a preparation under the Convention on Psychotropic Substances and therefore considered a ‘drug’. Since possession of a preparation containing THC, regardless amount, is a criminal offence according to Swedish law, we do not support a statement that THC in cosmetic products should be accepted. Furthermore, a cosmetic product containing THC should not be considered safe according to Article 3 CPR, regardless of the THC is synthetic or extracted from the cannabis plant.

Different parts of the cannabis plant

We question the necessity and relevance of dividing the cannabis plant in different parts when discussing the use of parts of the plant in cosmetic products. The legislation regarding cannabis is different in different Member States. A party to the Single Convention and the Convention on Psychotropic Substances is not precluded from adopting measures of control more strict or severe than those provided in the convention² and criminal law is not fully harmonised within the Union. According to the Single Convention, the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted are defined as a ‘drug’. In Sweden, all parts above ground (except the seeds), from which the resin has not been extracted, is regarded as narcotics (except in certain circumstances as stated above). Therefore, cosmetic products with parts of the cannabis plant that are not considered to be a narcotic in some Member States, can still be considered a narcotic in others even though it is not a prohibited ingredient according to entry 306 of Annex II to the CPR. In our view there could be a risk in stating that some ingredients are allowed when they in fact are not. This can for instance result in companies believing their products are lawful when in fact there could be a risk of committing a criminal offence in one EU Member State.

¹ In footnote 9 of the draft non-paper, it is stated that “The draft guidelines by the INCB annexed to the joint note state that a cannabis preparation is a preparation ‘which is also known as a cannabis-based medicine’.” Please note that the draft Guidelines on the international drug control requirements for the cultivation, manufacture and utilization of cannabis for medical and scientific purposes, which we assume you are referring to, has now been replaced by a minimum common standard. The new version does not contain the cited wording.

² Article 39 in the Single Convention and article 23 in the Convention on Psychotropic Substances