Thanks a lot for your email and the information therein.

We will reflect on the comments provided and revert to you if necessary

Kind regards.

From: Sent: Tuesday, March 29, 2022 1:31 PM

Subject: Spanish Comments on the draft Non-paper Cann

Dear all

We are writing in order to make comments on the document "Draft Non Paper on Cannabis". It's worth mentioning that we made our comments in conjunction with the Spanish Competent Authority on

Please, apart from commenting the text line per line (see attached file) we would like to make some general comments of the paper:

Firstly, we want to point out that the judgment in Case C-663/18, which its disputes in the main proceedings concerns the marketing in France of an electronic cigarette which contains CBD, was not intended to resolve the substantive question, the classification of CBD as not being a drug. It only gives a clear instruction to the French Courts to resolve itself this particular case when there are or not a risk associated. We are really surprised by the fact that a mere deliberation, which did **not include references to the regulatory framework governing cosmetics**, could lead to a change of criteria in the

On other hand, it is worth mentioning that the Single Convention on Narcotic Drugs 1961 not only classifies substances as narcotics, but also establishes the legal basis of a control regime of them, affecting many sectors, as for example chemicals, medicines, agriculture, customs, and as result different competent authorities are involved in its enforcement. Consequently, is important to have an official common interpretation on that issue, simply because if we have an unilateral interpretation of the Single Convention, we will find paradoxical situations like the following that could happen in Spain:

Taking into account that the Single convention, the law17/1967, 8th of April (national legislation) which update the current legislation on narcotics in line with the single convention of 1961 of United Nations, as well as International Narcotics Control Board (INBC) criteria, the substance CBD derived from extract or tincture of cannabis is considered include in the list I of the Single conventi

Consequently, its manufacture, import, export, distribution, commercialization, use and possession shall be limited to medical and scientific purposes (article 4 c single convention). Notwithstanding, CBD, whether obtained as an extract of the part non controlled of Cannabis sativa plant or artificially synthesized, shall not be considered as not being included in the Single Convention. Consequently, national competent authorities on narcotics could take measures against cosmetic products that contains derived from extract or tincture of cannabis, despite the fact that competent authority on cosmetic

As you can see, for the AEMPS that is competent authority on narcotics, as well as cosmetic products, is very difficult to apply the criteria on the draft paper.

Actually, the legal status of CBD derived from cannabis plant is under discussion in Horizontal Working Party on Drugs (HDG) ad hoc informal working group on the INCB Guidelines and in the INCB Intergovernmental Meeting on reporting and monitoring standards for the international drug control of cannabis and cannabis-related substances for medical and scientific purposes with Permanent Missions to the United Nations to find the common grounds to harmonize international drug control requirements for the cultivation, manufacture, and utilization of cannabis for medical and scientific purposes. The aim of these HDG ad hoc informal working group meetings is to exchange views between the Member States CNA and to explore potential common positions that Member States could then, at their discretion, voice at the next intergovernmental meetings organized by the INCB.

In order to find an official common interpretation, this issue should be addressed firstly in the context of the HDG. Only when they have reached a conclusion, we will be able to work in a technical document, which goes into detail about its practical application in the field of cosmetics

Kind regards

encia Española de Medic



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