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Directorate General "Health and Food Safety"
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Einschreiben mit Rückschein!

To the attention of the

- **Members of the "Working Group Novel Food" meeting 12 March 2019 in Brussels**
- **European Commission, Directorate General "Health and Food Safety"**

Vienna, 8 March 2019

**Re: Status of Cannabis sativa, CBD and Cannabinoids –
Forthcoming discussion in the Working Group "Novel Food"**

Dear Sir/Madam,

Experts of competent authorities gather on 12 March 2019 for the "Working Group Novel Food" to continue the discussion on the "status of Cannabis sativa, CBD and Cannabinoids". Consumer and patient organisations are anxiously following the debate in the forum provided by the Working Group as it will possibly prepare a consensus among Member States and the European Commission. Given that the argument is reaching a crucial stage of drawing a line between the novel and non-novel food status of cannabidiol and its derivatives, the "Allianz gegen Ignoranz" (www.allianz-gegen-ignoranz.at) – representative, one may claim, for consumers and patients across Europe – steps forward with the petition below to argue the case for a liberal approach in European food law towards cannabinoids. This letter is to draw your attention to the particular situation of patients under pain treatment, their interest in the availability of affordable CBD products as food and food supplements and the threat of creating monopolies for the pharma industry should hemp-products be pushed out of the market.

Situation in Europe

Following the discussion in the Novel Food Working Group meeting 16/10/2018, the European Commission lists Cannabis sativa and CBD in the Novel Food Catalogue, effective from January 2019. While not legally binding, the change of status instituted by the Catalogue listing makes the marketability of cannabinoid products considerably more difficult by possibly requiring a pre-market authorisation under Regulation (EU) 2015/2283 for a range of products that were previously freely available. Yet the matter is not yet settled and further discussion is still needed as the agenda of the Working Group will attest to.

As we understand it, the Catalogue suggests the following scaled categorisation:

- synthetically obtained CBDs → novel
- hemp and hemp-derived products containing cannabinoids → novel
- hemp seeds, flour and seed oil, protein powder from seeds → not novel
- leaves, flowers, extracts of different plant parts → ?

The status of hemp seeds, flour and seed oil has been cleared because a history of safe consumption has been proven, but also, because CBD levels seemingly occur 'naturally' (i.e., is not 'extracted') respectively CBD is not added or enriched in the product.

Final conclusions, however, are premature as still no decision has been taken under Article 4 of Regulation (EU) 2015/2283 to verify the status of hemp in all its forms.

Situation in the Member States

The approach of national authorities is far from uniform. While some Member States take a restrictive approach anticipating European solution, other countries are more lenient. After all, the previous entry in the Novel Food Catalogue suggested that most usages of hemp were not novel. It is certain, therefore, that the recent change causes widespread insecurity.

Situation in Austria

Medical drugs

In Austria only three THC-based medical drugs are available as prescription drugs (Dronabinol, Sativex, Canemes) and may be prescribed in cases of chronic pain, nausea and vomiting as well as multiple sclerosis. These drugs are exorbitantly expensive (for instance, 500 mg Dronabinol costs 450 EUR) and for many patients in need of pain treatment are unaffordable. Health insurance only reluctantly reimburses expenses (less than 8,000 people benefit from reimbursements while the Österreichische Schmerzgesellschaft estimates the number of persons suffering from polyneuropathy to be in excess of 300,000). It is hoped the situation may improve, or at the very least, that it is influenced by the recent European Parliament resolution of 13/2/2019 on use of cannabis for medicinal purposes. However, for the time being, consumers and patients have to look for other sources.

Food and food supplements

CBD is recognised as having anti-inflammatory and anti-epileptic effects, including anti-psychotic effects and is offered in the form of drops or capsules. CBD is not an addictive drug and there is no prescription requirement. Currently, there is no reimbursement of preparations by the health insurance because CBD has not been included in the Austrian drug tax. CBD has so far been available to patients in pharmacies, hemp shops and on-line shops. Recently, CBD in flower form has also been distributed via vending machines (to people over 18 years of age). CBD drops with 20% CBD in 10 ml oil costs around 150 EUR. CBD is therefore also relatively expensive, but cheaper than for instance Dronabinol.

Invoking alleged "clarifications reached at European level", the responsible Austrian ministry, on 4/12/2018, issued a decree on the legal status of CBD regarding food supplements and cosmetics, thereby anticipating the result of the ongoing discussion. The decree states:

"Extracts containing cannabinoids which are placed on the market as such or in food should therefore generally be considered as novel foods under Regulation (EU) 2015/2283 ['Novel Food Regulation']. Only authorised novel foods included in the Union list may be placed on the market as such or used in foods in accordance with the conditions and labelling requirements laid down in the list. No such authorisation is currently granted. Placing on the market is therefore not permitted."

As a result, Austrian consumers and patients now face the very real threat of being deprived of a non-pharma CBD products.

Points to consider

Our alliance asks the Working Group Novel Food to consider, on the one hand:

- the significant measure of uncertainty among consumers and patients, primary producers and processors and also market surveillance authorities in Austria and other Member States
- the very tangible threat of novel food regulations creating monopolistic market structures favouring pharma interests with all negative effects for prices and availability

On the other hand one should consider:

- the safe track-record of CBD food supplements
- the history of consumption predating 1997 and indeed proof that Empress Maria-Theresia of Austria received cannabinoid treatment as far back as in the 18th century
- the safe use of cannabinoids in third countries such as Israel, Canada and USA

Thank you for considering this submission and for including our coalition in the circle of affected stakeholders.

In the name of the Allianz

Dr. Peter Kolba

About us. The "Verein zum Schutz von Verbraucherinteressen – Verbraucherschutzverein" (VSV - www.verbraucherschutzverein.at) is an Austrian independent consumer organisation. Its aim is to defend the interests of consumers and of patients vis-à-vis national and European authorities and economic players. The VSV is registered in the Register of Interest Representatives (No. 385900434121-64). On the subject of CBD, the VSV has formed a joint venture with other patient organisations "Arge Cannabis in der Medizin" (ARSECANNA), "Verein Chronisch Krank", [REDACTED] and "Selbsthilfegruppe Schmerz". This „Allianz gegen Ignoranz“ (www.allianz-gegen-ignoranz.at) stands for the liberalisation of cannabinoids in medicine and self-medication. Their members include patients under pain treatment who may be prescribed THC, but supplement such treatment CBD in form of droplets respectively by inhalations of botanicals.