The European Industrial Hemp Association (EIHA) published a position paper to overcome the patchwork of CBD-regulation in the European Union

Cannabidiol (CBD) is one of the non-psychotropic cannabinoids in industrial hemp. In 2016, 30,000 ha were cultivated in the European Union. The last couple of years have seen growing interest in CBD. Cannabidiol not only has a plethora of beneficial health effects, but it also has no relevant side-effects, even when it is administered at high doses. CBD is increasingly used as a food supplement and in food supplement compositions, and as an ingredient in cosmetics, thereby generating new investments and creating employment in the cultivation and processing of hemp and hemp-derived products. Pharmaceutical products with CBD as an active ingredient have also been developed.

At the moment there is only a tenuous patchwork of CBD-regulation. Just two examples from the last weeks:

On the 4th October, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) started issuing letters to CBD suppliers advising them that CBD is being designated as a medicine and that sale of CBD products must stop within 28 days; effectively banning sale of CBD from the 1st November. The implication of these letters is that for CBD to be sold in future, suppliers will have to obtain either a 'marketing authorisation' or a 'traditional herbal registration' from the MHRA. Most of the companies contacted by the MHRA have said they will cease trading, but several of the largest CBD suppliers have stated they have not received any letter from the MHRA and will continue their business until they receive notification of a change in law. The UK Cannabis Trade Association (UKCTA) has secured a meeting with MHRA on 3rd November.

In Germany, as of 1st October, 2016, CBD-containing medicinal products became prescription-only-medicines without any restriction as to dosages or administration routes. This was by an amendment to the Regulation on Prescription Medicines ("AMVV"), following a previous recommendation by an expert group of the Federal Institute for Drugs and Medical Devices (BfArM). Regrettably there was complete disregard to the fact that substantial pharmacological effects of orally administered CBD cannot be observed at dosages under approx. 200 mg per day for an average adult, and that CBD is very well tolerated even at much

higher dosages. The chance to benefit from the versatile beneficial health effects of CBD at different dosage regimes was missed.

The European Industrial Hemp Association (EIHA) supports the development of a harmonized legislation in this field, to make sure that consumers are protected, to sustain the industry's current double-digit growth rate, to attract new investors and to boost product development. The legislation should avoid any restrictions for CBD and clarify that extracts and preparations from industrial hemp are not narcotics in the EU.

The European Industrial Hemp Association (EIHA) is strictly opposed to the attempts by a few pharmaceutical companies to make CBD a prescription-only drug. This only serves the interest of a few companies while damaging the young CBD industry. Such legislation would also restrict the access to CBD for many citizens, who are already profiting from CBD in food and cosmetics. It is EIHA's expectation that European and national authorities should not limit the use of CBD in pharmaceuticals (medicinal products) only. There is also no reason to regulate the access to CBD too rigorously, because of the wide spectrum of beneficial physiological effects of CBD and its favourable safety profile.

For different doses and applications of CBD, EIHA proposes a three-tier regulation: At high doses, CBD can be a medicinal product and should be regulated as such. At physiological doses CBD should be regarded as an OTC-product (= over the counter) or a food supplement. This approach is already applied for many substances, such as valerian, glucosamine, chondroitin(sulfate), Ginkgo Biloba, some vitamins and iron products. Low CBD concentrations and doses should be allowed in food products without any restrictions.

Additional aspects such as route of administration, indication area, maximum single / daily dose and pack size can be used to further fine-tune the regulation. The German BfArM already uses these aspects to differentiate and demarcate between prescription-only and e.g. pharmacy-only substances.

The full position paper of the European Industrial Hemp Association (EIHA) on: "Reasonable regulation of cannabidiol (CBD) in food, cosmetics, as herbal natural medicine and as medicinal product" (October 2016) can be found, signed and supported here: www.eiha.org/cbd-support

EIHA asks all patients and citizen profiting from CBD products to sign the position paper.