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European Commission

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Brussels, 17 May 2021

Dear Ms Weiss,

Thank you for your letter of 5 March 2021 enquiring about the regulatory framework on medicinal cannabis.

Let me stress that cannabis-based medicinal products should be placed on the market on the basis of the same assessment as any other medicinal products. The safety, efficacy as well as quality of product in question must be carefully assessed before the product is placed on the market. The requirements as regards Good Manufacturing Practice are fully applicable to these products. The EU pharmaceutical framework ensures that all medicinal products, independently of the origin of an active pharmaceutical ingredient or a place of their manufacturing, are of the required quality.

We are aware that in the absence of applications for marketing authorisations, some Member States allow the use of cannabis-based preparations for medical purposes at the national level, relying on the exceptions found in pharmaceutical legislation. The use of these preparations is then subject to Member State legislation.

We consider that the EU legislative framework for medicinal products provides the highest assurances for the quality, safety and efficacy of medicines. Therefore, we welcome the clinical trials with the cannabis based medicinal products as they will generate data supporting potential submissions of applications for marketing authorisations in the EU. This would contribute to ensuring the availability of cannabis based medicinal products and at the same time provide the highest assurance of the quality, safety as well as confirmed efficacy, of these products for the European patients.

Yours sincerely,

S. Kyriakides

MEP Pernille Weiss
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Electronically signed on 10/05/2021 10:34 (UTC+02) in accordance with article 11 of Commission Decision C(2020) 4482