

(DRU0109)

Written evidence submitted by Brains Bioceutical (DRU0109)

1. Please accept this submission in support of enhancing the UK's Life Sciences sector.
2. Brains Bioceutical (Brains Bio) has invested close to £40 million in the UK. As one of the world's few registered EU-GMP grade, natural plant-based CBD active pharmaceutical ingredient (API) manufacturers, our CBD API is being used in 15 clinical trials worldwide, including an MHRA in human study with King's College London. Clinical research using our CBD API is exploring the effects of CBD on treating COVID-19, epilepsy, anxiety, insomnia and muscle inflammation to name but a few indications. Brains Bio is the exclusive natural CBD API supplier for a Phase III clinical trial on refractory epilepsy. The marketing authorization on the Phase III epilepsy trial is anticipated early next year.
3. Through our wholly-owned subsidiary BSPG Laboratories, and our Cannabinoid Centre of Excellence, located in Discovery Park in Sandwich, Kent, we manufacture an API with 36-month stability data and have produced over 350 commercial batches with consistency. BSPG Laboratories is registered with the MHRA as an API manufacturer. We are expanding the BSPG facilities to increase our annual capacity and growing our facility from a 4000 sq ft facility to a 21,000 sq ft.
4. Our clinical research partners are relying on Brains Bio to manufacture other phyto-cannabinoid APIs under our EU-GMP license at BSPG to further advance the scientific narrative of phyto-cannabinoids health solutions. We have also secured an option to develop a third facility at Discovery Park for this purpose.
5. Our science team has developed natural plant-based APIs for Delta 8 THC and Delta 9 THC and are working on CBN cannabinoids for clinical research, but we cannot export these APIs due to current license restrictions. Under our current schedule 1 license with the Home Office, we can possess Tetrahydrocannabinol (THC) and CBN, but unlike CBD, THC and CBN are controlled substances under the Misuse of Drugs Act 1971, and cannot be exported to support the clinical research program.
6. Brains Bio is a key global leader in evidence-based Phyto-cannabinoid health solutions to enhance patient life and treatment options. We look forward to continuing to contribute to building the UK Life Science Sector. Our knowledge, experience and expertise are at the forefront of cannabinoid manufacturing and research and driving innovation in the cannabinoid space. Our request is to allow a pilot program exemption for BSPG Laboratories to support the life sciences sector and export THC from the UK. This would enable us to develop a third facility and keep investment in the UK and not other EU jurisdictions where the export of cannabinoids is permitted, thus allowing us to support clinical trial programs.

August 2022