

Lord Bates Lords Minister

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I replied on 13 July to your letter of 29 June about the Government's Psychoactive Substances Bill and its possible impact upon lawful research. I wanted to take this opportunity to update you on the work we have done over the summer - including with officials of your Academy and other representatives of the research sector - to advance this issue and the corresponding amendments we are making to the Bill. I am grateful in particular for the input from Victoria Charlton and Professor Ray Hill.

I hope my earlier letter and the Government's comments during the Lords debate reassured you and your letter's co-signatories that it is not the Government's intention to interfere in any way with *bona fide* research involving psychoactive substances through this Bill. The Government continues to attach a high priority to scientific research and are committed to not put in place unnecessary regulatory barriers that in any way impede this important work in the UK.

At the outset it is important to stress that only a limited amount of research activity was in the Bill's scope. The Bill only covers the supply (including its production, importation, exportation, offer to supply and possession with intent to supply) of a substance which is capable of producing a psychoactive effect in a person who consumes it. Therefore any research or supporting activity which does not involve a substance being consumed by a human is out of scope, for example, all *in vitro* testing and *in vivo* tests involving animals. In addition, for an offence to be committed an individual must know or ought to know that the substance in question is psychoactive: the unintended production of a psychoactive substance would not constitute an offence.

The Government undertook to build on the exemption of all potential in-scope research beyond 'investigational medicinal products' in Schedule 1, in readiness for the next stage of the Bill's passage through Parliament. Over the summer we discussed this issue with the Department of Health, the Medical Research Council, Government Science, the Health Research Authority, the Department of Business, Innovation and Skills and representatives from AMS and the wider research sector to agree how we can best exempt all bona fide research. Following this discussion the Government has tabled amendments to address this issue.

As you know, the Bill broadly defines a psychoactive substance. The Bill's scope is then narrowed by a schedule exempting certain substances and by the nature of each offence. We have concluded the simplest way to exempt *bona fide* research is to insert a second schedule listing exempted activities. These activities will include scientific research approved by a relevant ethics review or scrutiny body, whether it be the Health Research Authority's Research Ethics Committee or another approval body such as one appointed by a Secretary of State (or Minister from a Devolved Administration), a relevant NHS body, a body that is a Research Council, a research institute (including universities), or a registered charity.

From our discussions with partners we believe this approach will capture all in-scope research. It also should not impose any additional burden on researchers as we — and those we have consulted - understand all in-scope research routinely goes through such an approval process. We have been alert to not create any loophole, for example allowing the psychoactive substances market to pass consumption off as "research". We believe the requirement for approval from a properly constituted approval body should overcome this concern and underscore the *bona fide* nature of genuine and valuable research in this field.

I am acutely aware that we need to provide simple and concise messaging to the research community to clarify exactly what the Bill will and will not cover. My officials will take this forward and are very keen to work with your Academy and others in the research field to ensure we provide targeted and accurate messaging.

Thank you for bringing this important issue to our attention.

THE RIGHT HONOURABLE LORD BATES