



Home Office

Home Secretary

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Professor Les Iversen
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27 October 2015

Dear Professor Iversen,

PSYCHOACTIVE SUBSTANCES BILL

Thank you for your letter of 23 October, as well as your earlier letter of 17 August, on the Psychoactive Substances Bill. This reply also provides an update on progress following the recommendations in your earlier letter of 2 July.

At the outset I would like to thank you and your members for the time you have spent with Home Office officials over the summer working on various aspects of this Bill. I valued our discussion on 21 September and I know Home Office officials had a constructive meeting with your Technical Working Group on 7 October. I have also welcomed the Council's input on developing the Bill's forensic strategy with the Home Office's Centre for Applied Science and Technology, advising the department on the potential scope of the post-implementation review and your advice on our wider response. Your continued input will be essential to ensure the successful implementation of this Bill.

Building on our dialogue over the last few months, I am responding formally to your latest letter promptly, as well as to your previous advice of 17 August, to ensure that Parliament has the benefit of the Government's full response while the House of Commons scrutinises the Psychoactive Substances Bill this week.

The ACMD's letter of 17 August - defining "psychoactive substances"

The growth in psychoactive substance misuse coincided with the emergence of synthetic substances onto the UK market around 2008/9. The undoubted focus of this Bill is on those products. However, some natural psychoactive

substances are of course harmful (e.g. Ibogaine and Kratom) and if the Bill only covers synthetic products, the market may be driven towards natural products, or claimed natural products, more generally. I therefore have no desire to create this loophole and drive this market, just as the Misuse of Drugs Act 1971 has done with synthetic substances with new substances emerging which have been designed to evade controls.

The Council's earlier recommendation to limit the scope of the Bill to synthetic substances was driven by your concerns about the breadth of the definition and its consequences especially for herbal medicines. We have worked hard across Government, notably with the Department of Health and the Medicines Healthcare Products Regulatory Agency, to find a robust solution, to ensure that such products are fully exempted from the Bill. I understand that officials have kept you updated on the work to strengthen these. We are now proposing an amendment that will exempt all homeopathic and herbal products from the Bill. These will continue to be regulated by medicines legislation.

The ACMD also suggested narrowing the definition of a psychoactive substance to focus on substances with a pharmacologically similar response and comparable public health threat to that of controlled drugs. The term 'similar' places a burden on evidence gatherers/forensic experts to *prove* the similarity of a psychoactive substance to a drug controlled under the MDA 1971. There will almost certainly be discrepancies in how '*pharmacologically similar*' is interpreted which will cause issues similar to those posed by the analogue legislation used in the United States, namely differences in how forensic scientists, lawyers and courts interpret the term 'similar'. The New Psychoactive Substances Review Expert Panel considered and rejected the analogue model for this and other reasons.

Furthermore, I believe this approach would lessen the number of substances caught by the Bill, limiting the number of psychoactive substances caught to those which produce pharmacologically similar responses to substances controlled by the Misuse of Drugs Act 1971. Home Office officials believe nitrous oxide and alkyl nitrites are not pharmacologically similar to any current controlled drug. In addition, the European Monitoring Centre for Drug and Drug Addiction report a number of psychoactive substances such as dimethocaine, mephedramine, methiopropamine which, depending on how different experts define 'similarity', could reach a different outcome as to whether they are pharmacologically similar. I wish to avoid such uncertainty.

Finally, I appreciate you and members would prefer a harm assessment to be included in the Bill so that the Bill captures only psychoactive substances which pose a public health threat similar to that of drugs that are already controlled under the MDA 1971 and UN provisions. This would introduce a further subjective and evidential test for prosecutors who would have to show once again that the substances display similarities to controlled drugs in posing a comparable public health threat. A considerable challenge caused by the vast majority of these substances is the lack of harm data on both their

short and long term effects and as we have observed from New Zealand, agreeing a harms threshold is challenging.

Response to the ACMD's letter of 23 October

Recommendation 1 – the Home Office to provide the ACMD with an opportunity to review the draft of the forensic strategy and supporting guidance prior to the implementation of the new legislation.

Recommendation 4 - ACMD to continue to provide independent scrutiny and challenge to ensure that the forensic strategy is founded on and supported by a robust evidence-base.

I am greatly encouraged that you believe the Bill's forensic strategy, currently being developed, reflects the best available science in this area. I am confident that it will be able to prove that a substance is capable of producing a psychoactive effect.

The Council has a crucial role to play in relation to our forensic strategy, both its development and ongoing maintenance. My letter to you in May, at an early stage of the Bill's development, recognised the expertise which the Council has to contribute on this aspect of the Bill's implementation. Your advice and our discussions have only reinforced my view. I understand that the input you have already provided the Centre for Applied Science and Technology has ensured that we have made good progress in our readiness for proposed implementation next April. There will also be a role for the Forensic Regulator to make sure that the testing will be done to the same or equivalent quality standards as current forensic work. With your help, I believe that we can continue to build world-leading scientific capability and capacity in this area. I welcome your continued input and of course, we will seek the ACMD's views going forward in the way you recommend.

Recommendation 2 – the Home Office to consider the modification of clause (2) and the addition of proposed clause (4) to strengthen the definition and to make the definition more specific.

Recommendation 3 - in the event the amendments being proposed by the ACMD are not agreed, we recommend that the text is added as a permanent feature of the supporting guidance and forensic strategy associated with the Psychoactive Substances Act. It should be explicitly stated that the text was developed in consultation with the ACMD and that it would not be varied without further ACMD advice.

In drafting the Bill's definition of a psychoactive substance we have sought to balance the requirement to have a legally robust and accessible definition. The avoidance of criteria for manufacturers of these dangerous substances which allow them to try to circumvent (or indeed incentivise them to), the provisions of the Bill is paramount. I would also add that it would be highly unusual, if not unprecedented, to set out in legislation how an offence is to be proved – for instance, the Misuse of Drugs Act 1971 is silent as to what tests are required to prove whether a drug is controlled. Equally, any text which

itself is non- exhaustive (in this case, the proposed types of testing techniques and classes of substances) can provide uncertainty in legislation, in spite of its best intention.

I appreciate that the Council has not sought to suggest an alternative definition of psychoactivity to the one set out in clause 2(2) but only to add to it. The current definition in the Bill provides that a substance must be *capable* of producing a psychoactive effect. It is the Government's view that this test is robust and that it will be possible to evidence the offences in the Bill to the requisite criminal standard.

I fully accept that the underpinning science and testing technique will be key elements of the Bill's implementation. However, legislation is designed to be "technology-neutral". It is therefore my strong preference not to include any further text on the face of the Bill. The proposed addition to clause 2(2) of the Bill (as I understand it), of outlining appropriate tests to prove psychoactivity, and the inclusion for clause 2(4) of a non-comprehensive list of classes, can better contribute to the Bill's accompanying forensic strategy. Importantly, this will give us flexibility to update our forensic approach with the post implementation experience of enforcement partners, any unforeseen shifts in the psychoactive substances market and innovations in science, including testing methodology.

I am assured that you indicate in your advice that your proposed text will provide the blanket ban sought and will cover such harmful substances as nitrous oxide and alkyl nitrates. I re-iterate my response above, that the ACMD has a vital role in the forensic strategy. My officials will work with the Council to confirm the exact wording to fully understand its application at a policy and operational level, for inclusion in the forensic strategy and as well as what other document(s) this is most suited to.

I also wanted to revisit our progress in relation to the advice you provided in your 2 July letter and to further assure you of the impact your advice has had on the Bill and its implementation.

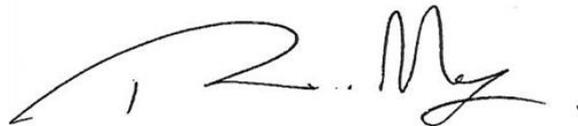
In response to your steer, we are :

- including a duty on the Secretary of State to consult the ACMD before exercising certain regulation-making powers;
- ensuring all bona fide scientific research is exempted from the Bill. We have worked closely with government colleagues and experts in the research field such as the Academy of Medical Sciences to develop this amendment;
- ensuring that the supply of legitimate medicinal products, including all homeopathic and herbal products are not captured. A further amendment will exempt activities by healthcare professionals in the lawful course of their duties. This exemption, together with the one for medicinal products, will ensure that all healthcare is entirely removed from the scope of the Bill;

- requiring the Secretary of State to publish a review on the operation of the Act 30 months after it comes into force. We will continue to discuss with the ACMD how this will be undertaken. Whilst it will be conducted by Home Office analysts, it will be published, and laid before Parliament and will be open to scrutiny;
- working with the police, NCA and other law enforcement agencies to ensure effective action is taken, intervening and seeking to close on and off line markets; and
- driving forward a comprehensive action plan on prevention, treatment and information sharing and ensuring that our approach to new psychoactive substances is in line with our balanced drugs strategy. We are building on our current approach to raise our ambition for recovery and tackle drugs as a key driver of crime. As a major partner, the ACMD will play a pivotal role in developing our approach and we look forward to consulting with you on this.

I have greatly valued the advice you have provided me throughout the summer on various aspects of this Bill. I appreciate you may be disappointed that I have been unable to accept all your recommendations, but your challenge has been welcomed and I believe we have a stronger Bill as a result. I look forward to continuing to work with the ACMD as we move towards the implementation of the Bill next spring.

I am copying this letter to Rt. Hon. Jeremy Hunt, MP, Secretary of State for Health Rt. Hon. Mike Penning MP, Minister for Policing, Crime and Criminal Justice and Rt. Hon. Jane Ellison, MP, Parliamentary Under Secretary of State for Public Health

A handwritten signature in black ink, appearing to read 'Theresa May', with a large, sweeping initial 'T' and a stylized 'M'.

The Rt Hon Theresa May MP