Written evidence submitted by Napp Pharmaceuticals

Thank you for the opportunity to be able to submit a response to this enquiry.

Napp Pharmaceuticals is one of a number of privately owned, worldwide, independent associated healthcare companies. Napp is a leader in the field of pain management and has been committed to furthering the understanding and treatment of pain for over thirty years. The UK Company has been based at Cambridge Science Park since 1983. The company employs over 700 people across the UK. At the end of 2010 the company was ranked 10th largest in the UK pharmaceutical industry based on GP prescription sales.

Which groups will be particularly affected by a ban on psychoactive substances? What steps can the Government take to educate these groups about the dangers? How will the Government explain the change in the legal status of these substances?

Napp fully supports the Government's aim of tackling the harm and preventable deaths that can be caused by new psychoactive substances. Napp believes, however, that in its current form the Bill could have adverse effects on producers and developers of legitimate medicines, (i.e. MHRA approved) and, consequently, on patients.

These concerns stem primarily from the definition of the term psychoactive substances. As has been widely discussed at each stage of the Bill's passage through the House of Lords, the definition of a psychoactive substance as a substance that is 'capable of producing a psychoactive effect in a person who consumes it' is far too broad. Whilst we are aware the definition is intentionally broad to keep ahead of the pace at which these substances can be created and altered, the broadness of the definition may also mean its unintended consequences are that legitimate medicines are captured within the scope of the legislation.

The current provision for exemptions does not provide enough assurance that substances with legitimate medical usage will not become restricted. Firstly, as noted by the Advisory Council on the Misuse of Drugs (ACMD), it would be almost impossible to list all possible desirable exemptions under the Bill. The difficulty of listing exemptions could mean that substances that should be exempt are accidentally missed off the list, which could cause great uncertainty, even if the mistake is then rectified. Even if the list was somehow exhaustive at the time of writing, keeping it up to date would present another near-impossible task, as new medicines are introduced onto the market frequently. This could create an environment in which medical professionals avoid prescribing new medicines, even if they would be the best option for a patient, because they are unsure of whether that medication or a component of that medication has yet made it to the exemption list.

Whilst the Bill gives the Secretary of State the power to 'vary' the definition of a substance in schedule 1, which defines exempted substances, presumably to allow for medical innovations, this power actually creates more problems than it solves. As highlighted in a report by the House of Lords Constitution Committee which was published in June, this power could mean that the Secretary of State was able to expand significantly the scope of the Bill by altering a definition. Overall, this could create a regulatory environment that is so difficult to keep on top of that both doctors and medical researchers suffer due to a perpetual state of uncertainty.

Further assurance is needed that the exemption will include all medicines prescribed on a named-patient basis, even those on the UK market which may have been tested in other countries but which have not been through UK systems. In order to reduce the possibility that this legislation will inadvertently remove options due to an environment of uncertainty in developing and prescribing new drugs, the exemption for medical products must be strengthened.

NAPP looks forward to seeing the amendments that the Government has committed to making to the Bill as it passes through the House of Commons which will 'strengthen' the medical definition, and hopes that they take into account the impact that an inadequate definition could have on medicine and patients. In the meantime, the Government must work closely with the ACMD as well as representatives from the pharmaceutical and medical research communities and patient groups, to ensure that a more satisfactory definition is reached.