AN BILLE UM SHUBSTAINTÍ NEAMHLEIGHEASACHA SÍCIGHNÍOMHACHA 2010
NON-MEDICINAL PSYCHOACTIVE SUBSTANCES BILL 2010

EXPLANATORY MEMORANDUM

(This Memorandum is not part of the Bill and does not purport to be a legal interpretation)

General

The purpose of this Bill is to establish a new body known as An tÚdarás Rialála um Shubstaintí Neamhleigheasacha Sícighníomhacha translated into English as the Non-Medicinal Psychoactive Substances Regulatory Authority (hereafter known as ''the Authority''). This Authority will regulate the sale, production, import, distribution and marketing of substances and products that can have an effect on perception, health and wellbeing when consumed or otherwise used by persons, referred to in the Bill as non-medicinal psychoactive substances. The Authority will have the power to ban or otherwise restrict substances and products within its remit that are demonstrably harmful. The Authority will liaise with the EU and other international bodies that deal with drug and harm reduction research and drug regulation and enforcement in order to ensure an approach consistent with international best practice and to aid international cooperation in substance control.

The main focus of this Bill is to address issues relating to ''legal highs''. These are products and substances that mimic the effects of prohibited drugs or are used as a substitute for them, but have not been made illegal under existing legislation. The fact that these products can be made available legally has led to the proliferation of so-called ''head shops'', also known as ''grow shops'' and ''smart shops''. These establishments exploit an unregulated market to sell non-medicinal psychoactive substances and products, many of which are potentially harmful, through retail outlets, home deliveries and internet sales.

The current system of identifying and banning substances has proven ineffective in dealing with these dangerous substances. Through cynical labeling and the masking of active ingredients the head shops have managed to establish an increasingly lucrative industry to the detriment of public health and well-being. This Bill will seek to protect public health and reduce the risk of harm from such products and substances through a new system of control involving evidence-based prohibition, regulation and licensing. The regulatory body it establishes will be given the authority to make decisions, based on a holistic consideration of factors relating to non-medicinal psychoactive substances. These decisions shall take into account scientific evidence, as well as other health, social, criminal

and public welfare factors relating to the substances. The composition of the Authority shall be such that the members will have sufficient qualifications, knowledge and experience to be able to make authoritative decisions of this nature.

The Bill provides for regulation of the sale, production, import, distribution and marketing of any non-medicinal psychoactive substances that the Authority deems not to warrant an outright ban. It requires those involved in the sale, producers, importers and distributors of non-medicinal psychoactive substances to apply for a license under Licensing Agreements regulating business conduct and providing for the imposition of sanctions for breaches of license conditions including fines or the suspension or withdrawal of licenses. The Bill also establishes that it will be an criminal offence to operate without a license, or while a license is suspended or withdrawn. It also provides for the setting of licensing fees, which it is hoped will part fund the operations of the Authority, at no more than €1 million.

The Bill will empower the Authority to initiate and administer a regulatory system involving a range of controls including sales controls, production controls, import controls, distribution and supply controls, product and marketing controls and consumer controls.

Under this regime controls will be differential in intensity, linked to risk of harm, including restriction and banning of substances where appropriate. Product controls will include dosage and preparation controls as well as price controls. Packaging controls will include child-proofing and packaging information (as to contents, safe dosage, positive and negative side effects, general and specific risks, contraindications, harm reduction advice, outlet identification, and contact details for drugs services including counseling). Supplier and outlet controls will regulate advertising and marketing, location and density, shared responsibility between suppliers and consumers, volume and sales rationing controls. Purchaser controls will include minimum age, degree of intoxication and permitted volume of purchase.

The legislation will also empower the Authority to establish a clearly defined hierarchy of sanctions for license infringements, including fines, suspension or loss of license, partial or total civil liability regarding customer behavior and will also provide for criminal sanction.

The Non-Medicinal Psychoactive Substances Regulatory Authority that this Bill establishes would be complementary to the Alcohol and Drug Research Unit of the Health Research Board, the National Drugs Strategy and all its committees and drugs task forces, and not a replacement for these bodies. It is essential that these organisations are adequately funded and resourced to ensure that the Authority can function successfully by drawing on their research findings and other expertise in addition to its own.

PART 1

Preliminary and General

This Part contains standard provisions and the necessary interpretations for the Bill.

Section 1 contains the short title. *Section 2* provides the necessary interpretation provisions. *Section 3* provides for the funding of the

Bill's provisions including through the use of license fees. *Section 4* provides for a commencement day no more than two months after the passage of the Bill and *Section 5* provides for the making of Ministerial orders under the Bill, every such order shall require the approval of both Houses of the Oireachtas and a referral to the Oireachtas Joint Committee on Health and Children may be made to facilitate this.

PART 2

Non-Medicinal Psychoactive Substances Regulatory Authority

This Part makes provision for the establishment of a new Non-Medicinal Psychoactive Substances Regulatory Authority (''the Authority'').

Section 6 makes provision for the membership of the authority, their appointment and composition, its status as a body corporate and a permanent secretariat. *Section 7* provides that the Authority shall be independent and *section 8* provides for the Authority to develop and issue its own procedural rules governing those aspects of the conduct of its functions that are not expressly provided for in the Bill.

PART 3

Functions and Powers

This Part makes provision for the principle functions and powers of the Authority.

Section 9 details the principle functions of the Authority. These include to identify and classify non-medicinal psychoactive substances with regard to the potential harm of each; to establish a non-medicinal psychoactive substances register on foot of this work; to control the substances by way of prohibition or regulation and licensing as appropriate; to introduce and implement a licensing system, covering the substances it has decided not to subject to a full ban, including the determination of license applications and the maintenance of a register of applicants and licensees; to conduct inspections, report any suspected offences to an Garda Síochána; and impose sanctions for breaches of licensing conditions.

Section 10 provides for the conferral of additional functions on the Authority over time and as appropriate and *section 11* provides that the Authority shall have all such powers that are necessary for or incidental to the performance of its functions under the Bill.

PART 4

Non-Medicinal Psychoactive Substances

This Part provides for the identification and classification of substances by the Authority, the registration of same, a mechanism by which the Authority may ban certain substances or provide for their regulation by way of Licensing Agreements and a ban on the sale of non-medicinal psychoactive substances to children.

Section 12 details the factors and considerations on which the identification and classification of substances by the Authority shall

be based. This includes an individual and social harm reduction imperative. *Section 13* provides for applications to be made for a decision by the Authority on the classification of emerging substances however such an application is not necessary for a decision to be made by the Authority. *Section 14* provides for the development and maintenance of a register of non-medicinal psychoactive substances and some of the details that must be included on the register.

Section 15 confers on the Authority a power to ban the sale, importation, distribution and production of a substance and in addition a power to impose a provisional ban where sufficient public health concerns exist to have effect while any further research on a substance that may be necessary is conducted. Under the current system where the Minister decides to ban a drug the effect of the ban is postponed for three months and subject to EU approval under the European Technical Standards Directive. This Bill provides that a ban imposed by the Authority will have effect on a provisional basis during that period in the interest of public health.

Section 16 provides for the development by the Authority of Licensing Agreements involving any categories and conditions of license that it deems necessary to regulate the sale, production, import and distribution of non-medicinal psychoactive substances. These shall include any conditions of practice and conduct, reporting transparency and compliance and any other requirements deemed necessary by the Authority having regard to the considerations under *section 12*. This section also provides that the Licensing Agreements will outline the respective license fees which shall be set at a level to cover the operational expense of the Authority and penalties and sanctions for breach. Under this section the Licensing Agreements may include but shall not be limited to provisions (*a*) prohibiting sale to intoxicated persons, (*b*) restricting the locations and hours of sale of licensee's operations, (*c*) prohibiting marketing of the substances in any form, (*d*) requiring appropriate standards of packaging, including packaging information, and specific health warnings, (*e*) requiring full traceability of goods, (*f*) requiring training and accreditation of Licensee's and their staff, (*g*) controlling the dosages, volume or quantities of particular substances that may be sold, (*h*) requiring certain physical conditions aimed at limiting the accessibility of substances, and (*i*) establishing price controls.

Section 17 creates a new offence. Under this section it shall be an offence for any person to sell any substance to a person under the age of 18 where there is reasonable cause to believe that the substance may be used for the purpose of intoxication, subject to constitutionally necessary defences. The penalty for such an offence shall be (*a*) on summary conviction to imprisonment of a term not exceeding twelve months or to a fine not exceeding €3,000 or to both, or (*b*) on conviction on indictment to a fine not exceeding €1,000,000 or to imprisonment for a term not exceeding 10 years or to both. This section also provides Gardaí with powers of confiscation.

PART 5

Licenses

This Part makes provision for license application and the registration of license applicants and holders.

Section 18 provides that the Authority shall formulate and publish rules, reflecting international best practice, outlining the

requirements an applicant must satisfy in order to obtain a license. *Section 19* provides that the Authority will set up and maintain a Non-Medicinal Psychoactive Substances Licensees and Applicants Register and outlines some of the detail this register should contain.

PART 6

Enforcement

This part deals with the enforcement of the Bill's provisions including searches, inspections, offences and breaches of licensing conditions.

Section 20 provides the Authority with the power to conduct searches and inspections of licensees' and license applicants' products, premises and related property without notice. Any suspected criminal offence will be reported to the relevant prosecuting authority. And the Authority will consult and cooperate as necessary with An Garda Síochána, local Joint Policing Committees and Revenue Customs Service to develop effective ways to monitor the operations of those who are not licensed.

Section 21 provides that it will be an offense under the law to sell, import, distribute or produce non-medicinal psychoactive substances without an appropriate license or on a suspended license. A person guilty of an offence under this section shall be liable on summary conviction to imprisonment of a term not exceeding twelve months or to a fine not exceeding €3,000 or to both, or on conviction on indictment to a fine not exceeding €1,000,000 or to imprisonment for a term not exceeding 10 years or to both.

This Section also provides that the Authority will establish and publish a range of acts or omissions which would constitute a breach of the Licensing Agreements and establish appropriate and proportionate sanctions for each act or omission based on the severity of the potential harm to individual health, well-being and society. And the Authority will have the power to issue fines to licensee for breaches of the Licensing Agreements of not more than €500,000.

PART 7

Appeals

This Part makes a limited provision for appeals to be made to the Minister for Health and Children against decisions of the Authority and for the Authority to report to the Oireachtas Joint Committee on Health and Children and the Minister.

Section 22 provides that decisions of the Authority may be appealed to the Minister, however the Minister may only overturn a decision of the Authority on the basis of clear evidence that to do so would be in the public interest and a decision of the Authority shall stand until such time as it may be overturned.

PART 8

Reports

Section 23 provides that the Authority shall make an annual report which can be referred to the Oireachtas Joint Committee and the

Minister including such information as they may request. It also provides that the Committee or the Minister may request additional reports from the Authority on specific issues from time to time, and the Authority may also publish reports on its own initiative.

Introduced by Deputy Aengus Ó Snodaigh,
Aibreán, 2010.

Wt. 47026. 647. 4/10. Cahill. (X56106). Gr. 30-15.