Tithe an Oireachtais

An Comhchoiste um Shláinte

Tuarascáil maidir le Grinnscrúdú ar an mBille um Rialáil Cannabais atá lena Úsáid chun críocha Íocshláinte, 2016 [BCP]

Iúil 2017

Houses of the Oireachtas

Joint Committee on Health

Report on Scrutiny of the Cannabis for Medicinal Use Regulation Bill 2016 [PMB]

July 2017

32H011

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Introduction

This is the report of the Joint Committee on Health's detailed scrutiny of the Cannabis for Medicinal Use Regulation Bill 2016, which aims to make cannabis available for medicinal use through licenced pharmacies.

The Bill was referred to the Select Committee on Health by order of the Dáil of 1 December 2016. The Joint Committee on Health decided to conduct Detailed Scrutiny of the Bill before it proceeded to Committee Stage.

Purpose of the Bill

The purpose of the Bill is to make cannabis available as a medicinal product for individuals who receive certification from a registered doctor. To that end, it proposes the foundation of a Cannabis Regulatory Authority which would regulate the sale of medicinal cannabis and oversee a system allowing pharmacies to receive licences to sell medicinal cannabis.

Procedural basis for Scrutiny

Private Members Bills referred to Select Committee are subject to the provisions of Standing Order 141(2) [Dáil] which provides that a Select Committee "shall undertake detailed scrutiny of the provisions of such Bills….and shall report thereon to the Dáil prior to Committee stage consideration…." unless the Committee decides in relation to a particular Bill that detailed scrutiny is not necessary.

Paragraph (3) of Standing Order 141 permits scrutiny of the Bill in Joint Committee, viz. "Nothing in this Standing Order shall preclude a Joint Committee from undertaking detailed scrutiny as set out in paragraph (2) and reporting thereon to both Houses prior to Committee Stage consideration of the Bill by the Select Committee."

Detailed Scrutiny

The Committee met on 5 April 2017 when it heard evidence from the Bill's sponsor, Deputy Gino Kenny, and on 13 April 2017 when it heard evidence from officials from the Department of Health, on their respective views on the content of the Bill.

The Committee's views on the subject of medicinal cannabis are also informed by the report it agreed on 19 January 2017[1]. In that report, the Committee noted that, despite encouraging medicinal possibilities offered by cannabis and cannabinoids, there is still a shortage of peer-reviewed evidence for the efficacy and safety of cannabinoid treatment for many conditions, and that potential benefits had to be balanced against risks.

While the Committee appreciates Deputy Kenny's statement that his aim in sponsoring the Bill is to alleviate unnecessary suffering, aspects of the Bill cause the Committee to be concerned that it may not be possible to reconcile it with the Committee's above-mentioned careful approach to medicinal cannabis.

Cannabis Regulatory Authority

Firstly, the Committee is concerned that the Bill's proposed establishment of a Cannabis Regulatory Authority to regulate cannabis, which would be deemed a medicinal product, would undermine the current regulatory framework for medicine in the State, which involves the Health Products Regulatory Authority and the Pharmaceutical Society of Ireland. The Bill would establish a parallel system of regulation, duplicating the functions of the current one, and would allow a substance which has not received authorisation from the HPRA to be considered a medicine – an unusual departure which would subvert the agency's regulatory authority, ignore its expert advice that cannabis is not capable of being authorised as a medicine[2], and could create an undesirable precedent.

The Cannabis Regulatory Authority would duplicate the functions of The Health Products Regulatory Authority [HPRA]. Advocates of the Bill state that the HPRA is not willing to regulate cannabis. It is not possible to regulate the whole plant

[1] Available here: http://www.oireachtas.ie/parliament/media/committees/health/32H003-Report-on-Medicinal-Cannabinoids.pdf

[2] As stated in "Cannabis for Medical Use – A Scientific Review", HPRA, 2017, https://www.hpra.ie/docs/default-source/publications-forms/newsletters/cannabis-for-medical-use---a-scientific-review.pdf?Status=Master&sfvrsn=7

extract of a plant which has over 100 varieties and several hundred components. Authorised medicines must be of high quality, safe and effective.

Removal of cannabis as a controlled substance

The Committee is also concerned that the Bill proposes to remove cannabis from the Misuse of Drugs Act 1977 as a controlled substance, meaning that it could have major unintended policy consequences, decriminalising cannabis in non-medicinal circumstances. This seems in conflict with the intention of the Bill which is to make cannabis available specifically for medicinal use as expressed in the title of the Bill. It is the view of the committee that this is not a safe course of action as the cannabis plant has many psychoactive effects which are potentially harmful.

The Bill is as much about decriminalising the use of cannabis as it is about promoting it for medicinal use. The Minister for Justice and Equality is the relevant Minister quoted in the Bill.

Framework of access to cannabis

Furthermore, the system of access to medicinal cannabis proposed in the Bill, appears to the Committee to be too loose to effectively guard against (a) leakage of supply to recreational users, (b) overuse by patients, and (c) unanticipated harmful use due to interactions with other medicines or other medical circumstances for individual patients.

This is largely because the level of involvement of medical professionals in patients' engagement with cannabis, as outlined by the Bill, is in the Committee's view insufficient. The Bill allows a doctor to certify a person as having a condition which can be reasonably treated by cannabis, without having to stipulate a dosage amount or a finite period of time for treatment. There is also no provision in the Bill for stipulating the type of cannabinoid product a patient should be treated with, even though different cannabinoid ratios have shown different efficacy for different conditions. There is no reference in the Bill regarding the medical indications for cannabis certification by a doctor other than the patient has a condition which a trial of cannabis or cannabis based product is a reasonable course of action.

Certification from a doctor that a patient "has a condition for which a trial of cannabis or cannabis-based product is a reasonable course of treatment to improve symptoms or cause of the condition"(section 32 of the Bill), for a product which has no authorisation by the HPRA, would raise many legal and medical indemnity issues. A certificate is fundamentally different to a prescription. Evidence was given to the Committee by the Bill's sponsor's adviser that a doctor's certification is to be used as evidence to protect the holder of the certificate from prosecution and unnecessary criminalisation if found in possession of cannabis.

Evidence was given to the Committee that regulation of medicinal cannabis was key to its availability, yet the Bill does not define what the term medicinal cannabis means, therefore it would be very difficult to regulate.

Embedded in the cannabis plant are cannabinoids, which act on the endocannabinoid system in the human body, and have medicinal properties. However, whole plant cannabis also contains many other chemicals which are psychoactive and potentially harmful. It is not possible to regulate the whole plant extract of a plant which has over 100 varieties and several hundred components. The isolation of cannabinoids which have proven medicinal beneficial effects and have scientifically proven efficacy and safety is the key to developing medicinal cannabis products which can be legally prescribed and dispensed.

Further, labelling of the product would indicate its contents however it is unclear how this would be achieved given the numerous varieties of cannabis plants and their multiplicity of components.

Although the Bill limits the maximum amount of cannabis to be sold per transaction as one ounce, the Committee cannot identify any provision which limits the number of transactions. The Committee also cannot identify any provision in the Bill for medical follow-up or supervision beyond initial certification, e. g. to monitor potential negative side effects or interaction with other medicines. The Committee is therefore worried that any individual who receives certification from a doctor once would then be able to buy as much cannabis as they want indefinitely, without continued medical supervision.

Normally medication is prescribed with reference to strength in milligrammes and gives instructions on frequency and length of use. Such stipulations are not mentioned in the Bill.

The sponsor of the Bill proposed that whole or full plant extract would be made available in whatever form, including smoking cannabis, when used for medicinal purposes. The method of consumption would at the patient's prerogative. It is the Committee's view that this would lead to the leakage of whole plant cannabis from medicinal use to recreational use in the general population.

The Committee also wishes to draw attention to the use of the word "consumer" in the Bill to describe medicinal users of cannabis, the Bill's use of imperial measurements and the fact that a previous conviction for possessing cannabis would not disqualify a person from holding a licence to sell cannabis, all of which it views as inappropriate.

Also, the Bill suggests that the proposed Cannabis Research Institute would commission research on cannabis for recreational use as well as medicinal use. Additionally the Institute would promote public awareness of cannabis and its safe use. This element of the Bill seems contrary to the purpose of the Bill.

Overall approach of the Bill

Although the Committee has outlined a number of discrete problems in the drafting of the Bill, some of which may be more easily fixed through amendment than others, the underlying approach of the Bill proposes a system of access to medicinal cannabis that is much looser than the Committee considers prudent. Therefore, a central element of the Bill is irreconcilable with the Committee's views on how medicinal cannabis should be approached. The Committee favours a gradual introduction of medicinal cannabis which is evidence-led for each condition that access is approved for, which is endorsed by the usual regulatory authority for medicines in this jurisdiction and which has the benefit of close monitoring by medical professionals of the effects of treatment.

In that regard, the Committee is cognisant of the HPRA's advice that "medical use of cannabis should only be initiated as part of a structured process of formal

on-going clinical evaluation by a medical consultant, in a limited number of clearly defined medical conditions.[3]"

The Committee has been informed that such an approach is being pursued by the Minister for Health and his officials. Department Officials told the Committee, at its engagement with them of 13 April, that an expert reference group has been established which is currently drafting guidelines to facilitate the use of cannabis treatments under an access programme, its work being informed by the HPRA's report. The Committee also understands that the Department will progress Statutory Instruments to advance the access programme. The Committee views such an access programme as a more careful and desirable method of introducing medicinal cannabis to Ireland, and therefore views the continued advancement of the Bill under scrutiny as duplicative and undermining of the access programme process.

[3] "Cannabis for Medical Use – A Scientific Review", HPRA, 2017, https://www.hpra.ie/docs/default-source/publications-forms/newsletters/cannabis-for-medical-use---a-scientific-review.pdf?Status=Master&sfvrsn=7

Implications of the Bill for existing legislation

Having received legal advice, the Committee is satisfied that enacting the Bill as it exists would create legislative contradictions between the Bill and existing Acts. Resolving such contradictions by amendment of this Bill, or of other Acts, appears to the Committee to be an onerous undertaking, quite apart from the further re-drafting which would be necessary to avoid undesirable policy consequences.

The Bill may necessitate amendment to the Health Acts 1947 to 2015, the Pharmacopeia Acts 1931 and 1977, the Poisons Acts 1961 and 1977 and the Pharmacy Acts 1875 to 1977 - and other legislation - affected by the medicinal prescription of cannabis.

Section 17 of the Bill relates to medicinal use retail licences and such licences may only be granted in respect of registered pharmacies. The law relating to pharmacists and pharmacies may therefore need to be amended, possibly extensively.

Problems and inconsistencies for criminal justice legislation which could be created by the enactment of the Bill include but are not limited to:

- Differing definitions of cannabis between the Bill and the Misuse of Drugs Act 1977, which creates a possibility that the differing interpretations could be exploited in the criminal justice context.

- The possible need for section 5(1) (b) of the Criminal Justice (Psychoactive Substances) Act 2010 and section 5 of the Misuse of Drugs Act 1984 (and Regulation 28 of SI 173 of 2017) to be amended to explicitly exclude medicinal cannabis from their prohibitions against promoting psychoactive and controlled substances, so that they do not conflict with section 6 (2) (e) and (f) of the Bill, which deal with the Cannabis Regulatory Authority's promoting understanding of medicinal cannabis.

- The Bill's creation of offences without prescribing corresponding penalties conflicts with the 1977 Act, which provides both offences and penalties.

- Sections 16, 18 and 19 of the Bill respectively provide for licences to wholesale, import, and cultivate cannabis. The Committee understands that

these would require the amendment of sections 3, 15, 15A, 15B, 17, 19 of the 1977 Act.

- Section 3 of the Criminal Justice Act 1994, which defines "drug trafficking", might need to be amended to include an exception for medicinal cannabis.

- Section 15 of the 1977 Act would need to be amended to allow a parent to give medicinal cannabis to their child.

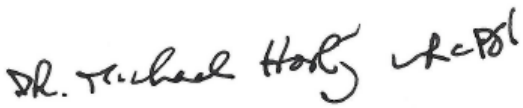
- The Committee understands that sections 42 and 43 of the Bill as drafted would legalise cannabis entirely, as the 1977 Act would cease to apply to cannabis. This seems to conflict with the intention of the Bill, which is to make cannabis available specifically in a medicinal context. If these sections were to proceed without significant amendment, they may also necessitate amendment of the Criminal Justice (Spent Convictions and Certain Disclosures) Act 2016, as well as having complicated implications for extradition law.

- Section 43 (1) of the Bill would alter the application of commitments made by Ireland under an international treaty, which would require corresponding action from Ireland at an inter-State level.

Recommendation to the Dáil

Based on its consideration, as outlined above, the Committee has determined that the Bill has technical issues and implementation difficulties, that it may have unintended policy consequences (including leakage of supply of cannabis to recreational markets and a lack of safeguards against harmful use of cannabis by patients), that there are major legal issues (the numerous amendments which would be necessary to reconcile the Bill with existing law would be onerous), and that access to medicinal cannabis in Ireland would be better achieved through an access programme and secondary legislation, which the Committee has been informed is under preparation.

Therefore, the Committee recommends that the Cannabis for Medicinal Use Regulation Bill 2016 **should not proceed to Committee stage.**



Michael Harty T.D.
Chair
Joint Committee on Health
12 July 2017

Appendix 1 – Committee Membership

Deputies:

Bernard Durkan (Fine Gael)

Dr. Michael Harty (Rural Independent Technical Group)

Billy Kelleher (Fianna Fáil)

Alan Kelly (Labour)

Kate O'Connell (Fine Gael)

Margaret Murphy O'Mahony (Fianna Fáil)

Louise O'Reilly (Sinn Féin)

Senators:

Colm Burke (Fine Gael)

John Dolan (Civil Engagement Technical Group)

Rónán Mullen (Independent)

Dr. Keith Swanick (Fianna Fáil)

Appendix 2 – Terms of Reference of Committee

JOINT COMMITTEE ON HEALTH

TERMS OF REFERENCE

a. Functions of the Committee – derived from Standing Orders [DSO 84A; SSO 70A]

(1) The Select Committee shall consider and report to the Dáil on—

(*a*) such aspects of the expenditure, administration and policy of a Government Department or Departments and associated public bodies as the Committee may select, and

(*b*) European Union matters within the remit of the relevant Department or Departments.

(2) The Select Committee appointed pursuant to this Standing Order may be joined with a Select Committee appointed by Seanad Éireann for the purposes of the functions set out in this Standing Order, other than at paragraph (3), and to report thereon to both Houses of the Oireachtas.

(3) Without prejudice to the generality of paragraph (1), the Select Committee appointed pursuant to this Standing Order shall consider, in respect of the relevant Department or Departments, such—

(*a*) Bills,

(*b*) proposals contained in any motion, including any motion within the meaning of Standing Order 187,

(*c*) Estimates for Public Services, and

(*d*) other matters

as shall be referred to the Select Committee by the Dáil, and

(*e*) Annual Output Statements including performance, efficiency and effectiveness in the use of public monies, and

(*f*) such Value for Money and Policy Reviews as the Select Committee may select.

(4) The Joint Committee may consider the following matters in respect of the relevant Department or Departments and associated public bodies:

(*a*) matters of policy and governance for which the Minister is officially responsible,

(*b*) public affairs administered by the Department,

(*c*) policy issues arising from Value for Money and Policy Reviews conducted or commissioned by the Department,

(*d*) Government policy and governance in respect of bodies under the aegis of the Department,

(*e*) policy and governance issues concerning bodies which are partly or wholly funded by the State or which are established or appointed by a member of the Government or the Oireachtas,

(*f*) the general scheme or draft heads of any Bill,

(*g*) any post-enactment report laid before either House or both Houses by a member of the Government or Minister of State on any Bill enacted by the Houses of the Oireachtas,

(*h*) statutory instruments, including those laid or laid in draft before either House or both Houses and those made under the European Communities Acts 1972 to 2009,

(*i*) strategy statements laid before either or both Houses of the Oireachtas pursuant to the Public Service Management Act 1997,

(*j*) annual reports or annual reports and accounts, required by law, and laid before either or both Houses of the Oireachtas, of the Department or bodies referred to in subparagraphs (*d*) and (*e*) and the overall performance and operational results, statements of strategy and corporate plans of such bodies, and

(*k*) such other matters as may be referred to it by the Dáil from time to time.

(5) Without prejudice to the generality of paragraph (1), the Joint Committee appointed pursuant to this Standing Order shall consider, in respect of the relevant Department or Departments—

(*a*) EU draft legislative acts standing referred to the Select Committee under Standing Order 114, including the compliance of such acts

with the principle of subsidiarity,

(*b*) other proposals for EU legislation and related policy issues, including programmes and guidelines prepared by the European Commission as a basis of possible legislative action,

(*c*) non-legislative documents published by any EU institution in relation to EU policy matters, and

(*d*) matters listed for consideration on the agenda for meetings of the relevant EU Council of Ministers and the outcome of such meetings.

(6) Where a Select Committee appointed pursuant to this Standing Order has been joined with a Select Committee appointed by Seanad Éireann, the Chairman of the Dáil Select Committee shall also be the Chairman of the Joint Committee.

(7) The following may attend meetings of the Select or Joint Committee appointed pursuant to this Standing Order, for the purposes of the functions set out in paragraph (5) and may take part in proceedings without having a right to vote or to move motions and amendments:

(*a*) Members of the European Parliament elected from constituencies in Ireland, including Northern Ireland,

(*b*) Members of the Irish delegation to the Parliamentary Assembly of the Council of Europe, and

(*c*) at the invitation of the Committee, other Members of the European Parliament.

(8) A Select Committee appointed pursuant to this Standing Order may, in respect of any Ombudsman charged with oversight of public services within the policy remit of the relevant Department or Departments, consider—

(*a*) such motions relating to the appointment of an Ombudsman as may be referred to the Committee, and

(*b*) such Ombudsman reports laid before either or both Houses of the Oireachtas as the Committee may select.

b. Scope and Context of Activities of Committees (as derived from Standing Orders) [DSO 84; SSO 70]

(1) The Joint Committee may only consider such matters, engage in such activities, exercise such powers and discharge such functions as are specifically authorised under its orders of reference and under Standing Orders; and

(2) Such matters, activities, powers and functions shall be relevant to, and shall arise only in the context of, the preparation of a report to the Dáil and/or Seanad.

(3) The Joint Committee shall not consider any matter which is being considered, or of which notice has been given of a proposal to consider, by the Committee of Public Accounts pursuant to Standing Order 186 and/or the Comptroller and Auditor General (Amendment) Act 1993; and

(4) any matter which is being considered, or of which notice has been given of a proposal to consider, by the Joint Committee on Public Petitions in the exercise of its functions under Standing Orders [DSO 111A and SSO 104A].

(5) The Joint Committee shall refrain from inquiring into in public session or publishing confidential information regarding any matter if so requested, for stated reasons given in writing, by—

(a) a member of the Government or a Minister of State, or

(b) the principal office-holder of a body under the aegis of a Department or which is partly or wholly funded by the State or established or appointed by a member of the Government or by the Oireachtas:

Provided that the Chairman may appeal any such request made to the Ceann Comhairle / Cathaoirleach whose decision shall be final.

(6) It shall be an instruction to all Select Committees to which Bills are referred that they shall ensure that not more than two Select Committees shall meet to consider a Bill on any given day, unless the Dáil, after due notice given by the Chairman of the Select Committee, waives this instruction on motion made by the Taoiseach pursuant to Dáil Standing Order 28. The Chairmen of Select Committees shall have responsibility for compliance with this instruction.