Joint Committee

on

Health

OPENING STATEMENT

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Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Introduction

Good morning Chairman and members. Thank you for the invitation to meet with the Joint Committee on Health to discuss the Medicinal Cannabis Access Programme.

I am joined by Prof Bryan Lynch who is a Consultant Paediatric Neurologist based in Children's University Hospital, Temple Street and who will have a clinical perspective on the issues to be discussed.

As background, the Primary Care Reimbursement Service (PCRS) is responsible for ensuring that eligibility is in place for qualifying persons for primary care schemes such as the General Medical Services (Medical Card and GP Visit Card) Scheme, the Drugs Payment Scheme, the Long Term Illness Scheme, the Dental Treatment Services Scheme (DTSS) and other schemes and arrangements. These schemes and reimbursement arrangements are essential to the operation of the Health Service.

PCRS is also responsible for making payments to Primary Care Contractors, suppliers of essential High Tech medicines and to Acute Hospitals and others across a range of schemes and arrangements. The proportion of the HSE's budget for 2021 that PCRS is responsible for amounts to €3.269bn. PCRS works hard to make the best use of the resources we are provided with and as a result its administration costs represent less than 1.5% of all its costs over the last decade.

Under the HSE National Service Plan 2021, PCRS was given the responsibility on behalf of the HSE, to commence the Medicinal Cannabis Access Programme, subject to the availability of suitable products and to establish arrangements to approve their use in relevant cases and record relevant information on a register as provided for in the legislation.

PCRS also has the responsibility to consider, pursuant to the requirements of the Health (Pricing and Supply of Medical Goods) Act 2013, applications for pricing and requests for reimbursement of MCAP products for individual patients.

There are currently 3 specified therapeutic indications (uses) set out in Schedule 2 of the MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) REGULATIONS 2019. Those specified therapeutic indications are:

- Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions.
- Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes.
- Severe, refractory epilepsy that has failed to respond to standard anticonvulsant medications.

In relation to the Operation of the Register, a practitioner (who has to be a medical consultant) can only issue a prescription for an MCAP product where an individual's name has been entered in the Register and what is called a "Cannabis for Medical Use Register" Number (or a CMUR number for short) has been provided by the HSE in relation to that individual.

Medical Consultants are therefore required to provide the HSE with the following information before they issue a first prescription:

- the name, address, date of birth and specified therapeutic indication (i.e. which of the 3 currently approved uses) for the person being treated
- the name, registration number and medical speciality of the notifying consultant
- such additional information as the HSE may require.

A person supplying a specified controlled drug (e.g. a pharmacist or pharmacy) is required to:

- provide his/her name and address to the HSE
- the name and address of the person who supplied him/her
- the followings details from the prescription
    - the date on which supply was made
    - the name, quantity, and where appropriate the dosage form and strength of the product
    - the dose supplied
    - the name, address and registration number of the Consultant prescriber
    - the CMUR number, name and address of the person supplied
    - the date of the prescription
- any further information required by the HSE

The HSE is required to record all of the above information in the MCAP Register and to assign CMUR numbers as required. The HSE is required to preserve all of the information in the Register for at least 5 years from receipt.

Schedule 1 of the MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) REGULATIONS 2019 (as amended) set out the products which can (subject to availability) be supplied under the Medicinal Cannabis Access Programme. There are currently 4 products listed in Schedule 1. The HSE does not decide which products are included in Schedule 1. The details of those products are tabulated and included at the end of this Opening Statement.

The suppliers of two products i.e. those of Cannepil and the Tilray Oral Solution have submitted final pricing positions to the HSE. The HSE confirmed acceptance of those prices in writing to the suppliers in June 2021.

The HSE currently expects that 1 product i.e. Cannepil will become available during October 2021. The suppliers of a second product, the Tilray Oral Solution have indicated their intention to supply the Irish market but have not confirmed when product will be available. The HSE understands the supplier of the other products does not currently have plans to supply the Irish market.

I now turn to reimbursement. In making general decisions on reimbursement, the HSE is required under the Health (Pricing and Supply of Medical Goods) Act 2013 to consider the following 9 criteria:

i. the health needs of the public
ii. the cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services (sometimes described as the opportunity cost for other services)
iii. the availability and suitability of items for supply or reimbursement

iv. the proposed costs, benefits and risks of the item relative to therapeutically similar items and the level of certainty in relation to those costs, benefits and risks
v. the budget impact of the item
vi. the clinical need for the item
vii. the appropriate level of clinical supervision required to ensure patient safety
viii. efficacy (performance in trials), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment
ix. the resources available to the HSE

The DOH has previously advised the HSE that it considered that Section 23 of the Health (Pricing and Supply of Medical Goods) Act 2013 appeared to be the most suitable legislative option for reimbursement on a managed access basis of community supply of the MCAP products.

Section 23 of the Health Act 2013 allows the HSE discretion, subject to such conditions as it considers appropriate, to make arrangement to supply an item to a patient notwithstanding that the item isn't on the reimbursement list, provided the HSE is satisfied that the patient requires the item for clinical reasons and provided there is no reimbursed item which is a suitable alternative for that patient. The intent of the HSE is therefore to utilise Section 23 to enable reimbursement of MCAP products where appropriate.

In practical terms, the HSE has designed an application form for prescribers to register a person to be treated. The application form will include all of the information required to register an individual on the MCAP.

The HSE will then assign a CMUR number and will also provide the applicant prescriber with a specific proforma prescription form which will contain the information legally required (including the relevant CMUR number) for the MCAP.

This concludes my opening statement.

Thank you

Schedule 1 of the MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) REGULATIONS 2019 (as amended).

"SCHEDULE 1

Regulation 2

Specified Controlled Drugs

Name of Cannabis product or preparation and brand name	**Dosage form**	**Concentration of THC (percentage, weight/weight or weight/volume)**	**Name of manufacturer**
Aurora High CBD Oil Drops	Oral solution	Less than 3% w/v (< 30mg/ml) This product also contains cannabidiol (CBD) 60% w/v (600mg/ml)	Aurora Cannabis Enterprises Inc. 4439 Township Road 304, Cremona, Alberta, Canada, T0M 0R0
CannEpil ™	Oral solution	0.5% w/v (5mg/ml) This product also contains cannabidiol (CBD) 10% w/v (100mg/ml)	MGC Pharmaceuticals d.o.o., Kamniška ulica 29, 1000, Ljubljana, Slovenia
Tilray Oral Solution THC10:CBD10 25ml	Oral solution	1% w/v (10mg/ml) This product also contains cannabidiol (CBD) 1% w/v (10mg/ml)	Tilray Canada Ltd., 1100 Maughan Road, Nanaimo, BC, V9X 1J2, Canada
Aurora Sedamen Softgels	Capsules	5mg/capsule This product also contains cannabidiol (CBD) less than 0.2mg/capsule	Aurora Cannabis Enterprises Inc. 4250 14th Avenue, Markham, Ontario, Canada L3R 0J3