Introductory remarks by the Department of Health on the Medical Cannabis Access Programme

to the Joint Oireachtas Health Committee.

Good morning Chair and members of the Joint Health Committee. Thank you for the opportunity to address the Committee on the Medical Cannabis Access Programme.

To put cannabis in context, it is a schedule 1 controlled drug under the Misuse of Drugs Act and is therefore subject to strict levels of control and access is allowed under licence for limited purposes only.

As the name would indicate the purpose of the MCAP is to enable access to a controlled substance which otherwise would not be legally available to patients. In this case the controlled substance is Tetrahydrocannabinol, known as THC, a psychoactive derivative of cannabis. Cannabidiol, known as CBD, another extract of cannabis, is not of itself a controlled substance and the MCAP is not intended as a means of accessing CBD-based products.

The Ministerial licence programme, in operation since 2017 is similar in that it enables, with the support of a consultant, a GP to prescribe cannabis-based products, where the patient is regularly monitored by a consultant.

The MCAP:

You will be aware that in recent years, in both Ireland and abroad, the subject of using cannabis products for medical reasons has become an issue of social and political debate, with calls for cannabis products to be made available to Irish patients.

Owing to this increasing interest, in December 2016, the Minister for Health requested the Health Products Regulatory Authority (HPRA) to provide scientific advice on the use of cannabis for medical purposes. Our colleagues in the HPRA will be able to elucidate further their findings in this review. Following publication of this HPRA report, the Minister for Health established an Expert Reference Group to provide clinical guidelines for the development of a Medical Cannabis Access Programme.

Acknowledging that some time has passed since the last review of the clinical evidence supporting the use of cannabis for medical reasons was done, the Department is currently working to commence a new clinical review that will continue the work of the previous clinical expert group. This review will seek to build on evidence found in the earlier study and will assess if there is to new information to support the addition of any other clinical indications to the MCAP.

Underlying legislation for the MCAP:

Following the recommendations of the HPRA review in 2017, and importantly the subsequent clinical guidance, the Department commenced work on developing a legislative basis for an access programme. This was done in consultation with the HPRA, and representatives from the expert reference group, and in June 2019 the legislation was enacted.

Statutory Instrument 262/2109 "The Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019" sets out the legal provisions for the operation of the Medical Cannabis Access Programme and the legal obligations for healthcare professionals and commercial

operators. It also sets out how the access programme will work, who can avail of it, how it will be operated by the HSE and how cannabis-based products, made from whole dried flowers of the plant, are accepted for use under the programme and placed on Schedule 1 of the Regulations SI. It is a pilot programme for 5 years and may be extended for a further period.

My colleagues from the HPRA can assist the Committee with questions on the process leading to inclusion of a product on the Schedule for use under the MCAP. It is the Minister for Health, who ultimately decides if a product goes on the Schedule. However, it is the sole responsibility of the supplier to apply to be considered for inclusion on the MCAP. There are currently four cannabis products on the Schedule and two more are to be added to Schedule 1 of the Regulations in the coming weeks. I understand that one of the products on the schedule, namely Cannepil, is expected to be available in October.

Subsequent to the introduction of the necessary legislation the Department has been working with the HSE who will, pursuant to the requirements of the SI, operate the Register of consultants and patients who will access the Programme. This engagement culminated in the MCAP being made part of the HSE Delivery Plan for 2021. In July it was announced that the HSE was ready to accept registrations of clinicians and their patients as required under the Regulations. Our colleagues from the HSE will be able to advise as to how the MCAP will operate in practice.

Ministerial Licence Programme

To meet the clinical demand for medical cannabis prior to establishment of the MCAP, the Minister for Health initiated in 2017 a programme whereby licences, granted under section 14 of the Misuse of Drugs Act, could be issued to practitioners on behalf of patients where the clinician could prescribe, import, possess, supply, and administer the controlled substance listed in the licence. A detailed application is required from the clinician, describing the indication the patient has, the fact that all other meds have been exhausted, or are no longer adding value to the quality of life of the patient and advising that they are prepared to prescribe cannabis oils and monitor their patient while using such products.

Such applications must also comply with recommendations made by the CMO who advised that the granting of an individual licence under the Misuse of Drugs Act for the use of cannabis for medical purposes by the Minister for Health sets aside the usual regulatory processes which are in place to protect the public and which ensure that only those medications which have been found to be both effective and safe are made available to the public.

Therefore, it is crucial that the granting of any such licence takes due care and consideration of the potential unintended consequences associated with the prescription of cannabis, a Schedule 1 controlled drug, for medical purposes, and that its use is endorsed by a consultant who is familiar with and responsible for the care of the individual for whom the licence application is being made. The CMO also noted that the independence of the doctor-patient relationship is a fundamental principle upon which medical practice is based and that it would be neither appropriate nor ethical for the Minister for Health to seek to influence this relationship.

Currently 192 licences have been issued in respect of 67 patients. The products prescribed are all sourced from a pharmacy in the Hague, called Transvaal Apotheek. The products are compounded by the pharmacy itself. Transvaal is a well-established GMP facility and is a reliable supply chain for clinicians and their patients. The Netherlands authorities however do not allow the export of cannabis

oils from the Netherlands to wholesalers or pharmacies, but they do allow individual prescriptions to be dispensed. Owing to the Dutch authorities' restrictions it is not open to the manufacturers of those cannabis-based products to apply to the HPRA to have their products included in schedule 1 of the Regulations.

In that regard representations were made by the Minister for Health to the Dutch authorities to request that the products could be commercially imported for inclusion on the MCAP. However, Dutch authorities stated that "magistral preparations may only be provided directly to patients or their representative on the basis of a prescription". Notwithstanding this the patients who are currently being treated with these products can continue to access them under the Ministerial Licence issued to their clinicians.

Due to Covid related travel restrictions, in May 2020 the Department put in place a courier system to facilitate the collection of products from the Netherlands for delivery directly to patients' homes. A decision has been made to retain this method of supply for patients accessing cannabis-based products in this way. Additionally, in July of this year, a direct funding scheme for eligible patients was commenced between the HSE and the dispensing pharmacy in the Netherlands. The pharmacy now directly invoices the HSE, and this removes the need for eligible patients or their families to pay for products upfront and subsequently seek reimbursement.

Conclusion

I hope the above has given you an overview of the MCAP and Ministerial Licence regime. Colleagues from the HSE will speak on the operation of the MCAP and any reimbursement questions you may have and HPRA colleagues will discuss how products get accepted for entry onto the MCAP.

Thank-you Chair.