Oireachtas Joint Committee on Health: 29 September 2021

Health Products Regulatory Authority Opening Statement
Joint Committee on Health
Medical Cannabis Access Programme

Good morning Chair and members of the Joint Health Committee.

We welcome the opportunity to come before you again to provide the Committee with information on the Medical Cannabis Access Programme (MCAP), the HPRA's role in this, and to answer any questions you may have on the programme.

In setting the context to our discussion today it is important to be clear on the status of the products that may be considered under this access programme, what they are, and importantly what they are not.

MCAP Product Status and Limitations in Their Use

In doing so, it may be helpful to return to some key aspects of the HPRA's 2017 review. The review considered the scientific data available at that time in relation to medical use of cannabis, which was extremely limited and fell well short of the standard and level required for a medicine to receive market access.

The review concluded that from a policy perspective should the Minister consider it in societal interest to establish a cannabis access programme, this should be in a limited set of circumstances for three specific medical conditions where it could be considered [spasticity associated with MS, intractable nausea and vomiting associated with chemotherapy and severe, refractory (treatment-resistant) epilepsy that has failed to respond to standard anticonvulsant medications].

A key recommendation for the programme was that it would need to take into account that access should only be provided where patients with the specified conditions have a clear unmet clinical need, meaning that they have failed to respond to treatment with all available authorised medicines. These limited recommendations were also based on the fact that the safety and efficacy data available did not support wider access.

The report also advised that the cannabis based products that may be made available through such a programme should not be confused with authorised medicines and are not equivalent to them. Authorised medicines undergo comprehensive clinical and quality evaluation, including clinical trials, to assess their safety and efficacy. The data generated from these studies is reviewed by scientists and companies to determine if there is a positive benefit / risk ratio and, if so, this data is submitted as part of the application for authorisation. The application is reviewed by medicines regulators, such as the

HPRA, to establish if they agree with the conclusion of the benefit / risk assessment. Where this is the case, the medicine is authorised.

Not meaning to detract from our focus on cannabis, but something perhaps the pandemic has shown in a very real way is how this process for authorisation of medicines works in practice. It has also increased the public understanding, appreciation and value of this process.

Authorised Cannabis Medicines

As the Committee members are aware, there are two cannabis-based products that are authorised as medicines. These are Sativex Oromucosal Spray for the treatment of spasticity in MS and Epidyolex Oral Solution for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex. Both products have met the standards and level of data required to receive a marketing authorisation. As such, these are quite distinct and do not fall under the scope of the MCAP.

Role of the HPRA in the MCAP

Provision for the MCAP was made under Regulations developed by the Department of Health in 2019. These set out how the access programme operates in terms of prescribing, supply to patients, and subsequent patient monitoring. They also define the criteria a cannabis-based product must meet in order to be considered for inclusion. The Regulations are importantly supported by clinical guidance that was generated by an expert reference group convened by the Department of Health in 2017.

This publically available guidance underpins the introduction of the access programme. It highlights a very important point around the decision to enrol a patient in the MCAP and that is that the relationship between the patient and the doctor is paramount in terms of clinical oversight. That clinical oversight allows for consideration of critical issues such as disease progression, whether all conventional treatment options with authorised medicines have been exhausted, and the doctor's decision as to whether these products may then be a suitable option for their patient.

The role of the HPRA in the MCAP is quite distinct and different from the role that we have with respect to the authorisation of medicines. While we receive and review applications from companies seeking to supply cannabis based products in Ireland via the programme, the extent and nature of this is very different. It involves initially reviewing the product applications against the criteria set out in the Regulations. The key requirement for accepting a product onto the programme is that it must be approved for supply in another EU Member State and is being supplied in that State. This is a way of providing access for Irish patients to cannabis-based products that are available to other EU patients and that could previously only be obtained by travelling out of the State. It acknowledges the reviews performed by other Member States and does not seek to create additional barriers where these reviews have already been conducted.

Other requirements are that THC limits are not exceeded and that the packaging and labelling is sufficient in terms of detail to support safe and effective dosing and product use. It is also our role to ensure that products are aligned to the published clinical guidance.

When our review is complete, we make a recommendation to the Minister where an application meets all of the above criteria. The final decision as to whether or not the product is included on the MCAP rests with the Minister.

It is important to note, as per the criteria in the Regulations and the overarching principle of the clinical guidance, applications can only be made under the MCAP where an equivalent authorised cannabis-based medicine is not available.

MCAP State of Play

Since the Regulations came into force in June 2019, we have received 34 product applications. Of these, four cannabis-based oils have been placed in Schedule 1 of the Regulations (which permits them to be used under the MCAP) and two dried herb products have concluded the HPRA review and are with the Minister for final decision. Five are currently under active review. In addition, eleven have been withdrawn or paused by the applicant company themselves. In the case of the remaining 12 applications, the company has not met either the legislative criteria or the clinical guidelines and these have been placed on hold by the HPRA as a result. We are continuing to work with a cohort of these companies on these issues.

The HPRA provides significant support to prospective applicants through guidance on both the legal framework and the product criteria to be met in advance of submission of an application. In all cases, we have direct meetings with these companies to advise and support their applications. The provision of this support also continues throughout the application review process.

The first cannabis-based products are expected to be available to Irish patients through the MCAP from mid-October 2021. Once these are accessed by Irish patients, the HPRA will receive any reports of suspected adverse events and review them for any signals of concern regarding the safety of the products. The HPRA will also have a role in investigating any quality issues that may arise and coordinating any market action required.

Thank you Chair.

29th September 2021