Health Products Regulatory Authority - Opening Statement

Joint Committee on Health, March 7th 2017

Good morning Chairman,

My name is Lorraine Nolan, Chief Executive of the Health Products Regulatory Authority (HPRA), the regulator of medicines and other health products in Ireland, with a primary role in the protection of public health. I am joined by my colleague Elaine Breslin, Clinical Assessment Manager. Further to our statement to the Committee on the 24th November 2016, we are pleased to discuss the HPRA report, 'Cannabis for Medical Use- A Scientific Review', which was submitted to the Minister for Health on the 31st January last and subsequently published by the Minister on the 10th February.

As the Committee will be aware, in November last year the Minster requested the HPRA to provide scientific advice on the use of cannabis for medical purposes. We were also requested to review the situation regarding the medical use of cannabis in other countries.

The role of the HPRA includes the evaluation of the benefits and risks of medicines on the basis of scientific evidence, prior to granting a marketing authorisation. The evidence for the use of many cannabis products is insufficient to permit a conventional benefit risk evaluation, or authorisation as medicines. As such, we have concluded as an outcome of our review that we cannot recommend widespread access to cannabis for the treatment of a range of medical conditions. However, we have advised that access could be facilitated under appropriately-controlled circumstances where adequate assurance of patient safety and follow-up can be provided.

Since the publication of the report, a policy decision has been made by the Minister to provide access to cannabis for medical purposes for defined medical conditions. He has indicated his intention to proceed with the advice of the HPRA.

In conducting our review of medical use of cannabis, the HPRA convened an expert working group comprising relevant clinical experts and patient representatives. The working group provided valuable support and context through the sharing of insights from both patient and clinical perspectives on this issue.

The conclusions of the review are comprehensively outlined within the published report which has been circulated to the Committee with my opening statement. For the purposes of today's discussion, I would like to outline the key considerations which are as follows:

1. To date there is an absence of scientific data demonstrating the effectiveness and safety of cannabis products. Of importance, there is insufficient information on the treatment of long-term medical conditions, such as those for which there is a public focus. In addition, most cannabis products available under international access schemes do not meet pharmaceutical quality requirements for medicines.

2. The review highlighted significant gaps between the public perception of effectiveness and safety, and the regulatory requirement for scientific data which is mandatory to determine the role of cannabis as a medicine. Any proposal to circumvent the medicines regulatory system, established by law, would require careful consideration, so as to avoid unintended consequences, and lower standards of patient protection.
3. The best outcome for patients is the development of authorised (or those capable of being authorised) cannabis-based medicines where the safety, effectiveness and quality can be assured, and understood by the patient and healthcare professionals. In this way, doctors can take account of side effects, and interactions with other medicines, and patients have medical oversight for their cannabis treatment.
4. If cannabis products that are not capable of being authorised as medicines, are made available through an access programme, patients and healthcare professionals will need to be conscious of the limitations of the programme in assuring the safety, quality and effectiveness, as compared with what would be expected for an authorised medicine.
5. Access to cannabis for medical use, should recognise patient need, be evidence-based, and fit with clinical practice. Therefore, it is advised, that treatment with cannabis is only permitted under a controlled access programme for the treatment of patients with;

    a. Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions whilst under expert medical supervision;
    b. Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes whilst under expert medical supervision;
    c. Severe, refractory (treatment-resistant) epilepsy that has failed to respond to standard anticonvulsant medications whilst under expert medical supervision.

In respect of the possible use of cannabis for the three specified medical conditions, the HPRA has not only reviewed the scientific literature, but has also advised on the practical steps that could be taken to provide access for Irish patients.

To this end, we recommend the introduction of a monitored, 5-year cannabis, access programme. Such a programme is necessary both to maximise the safe and effective use of cannabis as a medical therapy for an individual patient and to minimise the potential negative impact of wider access on society. It is proposed that the programme should run for a period of five years, with a centralised data collection point and regular reports to the Department of Health. This information will provide data on the medical use of cannabis and the supply needs in Ireland. The programme will also provide an appropriate level of monitoring and accountability for the cannabis products supplied.

Specific elements of the access programme should include:

- Patients treated with cannabis should be under the care of a medical consultant who has expertise and experience in the treatment of the specified condition, and who is responsible for the monitoring and follow-up of the patient;

- Authorised cannabis-based medicines should be considered for treatment in the first instance. This includes medicines not authorised in Ireland but approved for use in other countries. Investigational cannabis-based products subject to appropriate quality control requirements, could be sourced and used in the treatment programme, when standard treatments have been unsuccessful and alternatives are not available in Ireland;
- Doctors, pharmacists and patients should be registered under the programme, and data collected on the use of cannabis in these patients;
- Patients should be educated on the correct use of the cannabis for medical purposes, the benefits and risks involved, how to report side-effects, and the care and safe disposal of cannabis products;
- Doctors and pharmacists should be supported to facilitate prescribing and dispensing.

This proposal for a cannabis access programme provides a strong framework that can inform the future direction of access to cannabis for medical purposes. Further scientific research will be key to determining that future direction. While, there is significant involvement of scientific researchers in Ireland, more clinical, human-based research is needed. We envisage that this access programme can be adjusted and widened as clinical experience and scientific knowledge develops, and as more cannabis-based medicines become available. The HPRA is committed to assisting access to cannabis for medical use, in so far as we can, within the context of our remit.

The implementation of the access programme would be a significant move for Ireland, as we align ourselves with a number of our European neighbours. In the course of the HPRA review, 40 countries were surveyed. In Europe, 16 countries do not have any access programmes, 9 have programmes for exceptional use similar to that advised by the HPRA, and 3 countries have wider access programmes.

I have previously highlighted that the proposals in the report were accepted by the Minister, who has committed to progress the implementation as a priority. There are a number of factors that will be required including legislation, support for patients and healthcare professionals, and identification of suitable quality-controlled cannabis products.

A new legal framework for cannabis for medical use will require time to develop, and needs to be done in a manner that is effective and best meets both patient and societal needs. There is already provision within the existing legislation for prescribing in limited circumstances, subject to a licence from the Minister.

Supporting patients and healthcare professionals is vital to the implementation and the HPRA understands that the Department of Health will consult with relevant stakeholders.

The HPRA has, as part of its review, identified potential product sources. Further work is underway in this area.

Since publication of the report, the HPRA has met patient representatives, TDs, and their advisors, and responded to queries from members of the public and the media. We consider that it is important that patients and healthcare professionals have access to the information that we can provide on medicines, and the background to the HPRA's proposals. In addition, we are committed to continuing to engage with the Department of Health to achieve effective and timely implementation of the proposals.

In conclusion, the HPRA advises that cannabis for medical use, should only be initiated as part of a structured process of formal on-going clinical evaluation in patients with the clearly defined medical conditions. This position is based on current scientific evidence and will be kept under review.

Thank you Chairman and we will be happy to address any follow up questions.

Supporting submission: Cannabis for medical use- A scientific review