STATES OF JERSEY

MEDICINAL CANNABIS: RIGHT TO PRESCRIBE BY MEDICAL PROFESSIONALS (P.113/2018) – COMMENTS

Presented to the States on 5th November 2018
by the Minister for Health and Social Services

STATES GREFFE

COMMENTS

Members are asked not to support Deputy Tadier's Proposition – P.113/2018.

Deputy M. Tadier of St. Brelade is asking that all medical professionals with the right to prescribe be permitted to prescribe cannabis and various cannabis-derived products.

The extent to which cannabis and cannabis-derived products have a medical benefit remains subject to debate. Jersey, like other jurisdictions, is therefore taking a cautious, step-by-step, approach in this area.

Legislation is currently being drafted which will enable certain specialist doctors in Jersey to legally prescribe quality-assured (i.e. manufactured or produced to good manufacturing practice standards) cannabis-derived medicinal products, despite these products not being what is termed 'authorised' or 'licensed' medicines. At this time, the draft legislation will not enable G.P.s to legally prescribe these products. This reflects the advice provided in January 2018 by the Misuse of Drugs Advisory Council to the Minister for Health and Social Services. The Council is considering the issue again at its meeting on 20th November.

This is a similar position to the UK, where the decision to prescribe these unlicensed products must be made by a specialist doctor – not a G.P. These doctors focus on one field of medicine such as neurology, pain or paediatrics, and are listed on the General Medical Council's specialist register. Prescribing in the UK is therefore restricted to consultants only.

Consultants must make decisions on prescribing cannabis-based products for medicinal use on a case-by-case basis, and only when the patient has an unmet clinical need that cannot be met by licensed medicines. Patients under the care of a specialist are encouraged to discuss their treatment plan with them.

This approach in Jersey and the UK is governed by the fact that these products are unlicensed medicines. This means the product has been manufactured without a marketing authorisation ("MA") from the Medicines and Healthcare Products Regulatory Agency ("MHRA"). (The MHRA is the UK's medicine licensing authority – Jersey's medicines legislation reflects the UK licensing regime.)

An MA (or product licence) is granted by the MHRA only when a medicinal product has been proven to be safe and effective following controlled clinical trials. The MHRA recommends that unlicensed products should only be used when existing licensed medicines are not appropriate to meet patient needs, and this is also echoed in guidance from the General Medical Council.

Prescribing and dispensing of unlicensed products comes with additional professional responsibilities for both the prescriber and the dispensing pharmacist. Without a marketing authorisation, there is no MA holder to take responsibility for any adverse reactions associated with the product's use, and this means any liability rests with the prescriber.

Similarly, without marketing authorisations, unlicensed products do not benefit from the data generated as part of the licensing application process. There is no clinical trial data to demonstrate safety and efficacy of the formulation, what the optimum dose and

frequency of administration are, or what the short- and long-term side effects might be. In addition, there are limited stability studies to support a clear expiry date. Frequently, unlicensed products come with no detailed patient information, which would also ordinarily be produced as part of the application for an MA.

Given these issues, it is imperative to recognise the limitations and risks of using unlicensed products. These can best be met by limiting those medical practitioners who can prescribe them to those in the best position to employ strategies to minimise any potential risks and to balance these risks against patient need. They are best placed to ensure that such unlicensed products are used appropriately and safely by both professionals and patients.

The Head of the Pain Clinic at Jersey's General Hospital is fully supportive of this arrangement, stressing the need for a proper medical pathway to facilitate informed consent in a controlled situation. This involves assessment by a multi-disciplinary team, including physiotherapists, psychologists and occupational therapists, and attendance at a half-day training event. G.P.s can provide valuable input into such arrangements, but the consultant-centred approach avoids leaving G.P.s exposed from prescribing an unlicensed product, and relieves them from any pressure to do so. I am not aware of any requests from G.P.s to take on this prescribing authority. The Misuse of Drugs Advisory Council will keep the prescriber arrangements under review, and I will always consider any such advice it may provide.

All doctors are currently legally able to prescribe Dronabinol, Nabilone and Sativex, as these are authorised medicines, having undergone clinical trials to confirm safety and effectiveness. This has been the case for over 10 years. Epidiolex will soon receive its authorisation as a medicine and, as a consequence, will also be able to be legally prescribed by any doctor.

It is important to differentiate between being able to legally prescribe and the subsequent prescription being available free of charge to patients. These are 2 separate issues. G.P.s can legally prescribe Sativex, Nabilone or Dronabinol, but only on a private prescription basis, with the patient paying the full cost of the medicines supplied. Some specialist hospital consultants are able to prescribe Sativex free of charge to patients where it is clinically appropriate to do so.