

STATES OF JERSEY



BEDROCAN BV: POSSESSION FOR TREATMENT PURPOSES – PETITION (P.126/2014) – COMMENTS

**Presented to the States on 8th December 2014
by the Minister for Health and Social Services**

STATES GREFFE

COMMENTS

While this is a proposition about the appropriateness of issuing a special licence for the use of the cannabinoid-based product Bedrocan, we must not forget that at the heart of this debate is an individual patient suffering with a serious condition.

Part (a) of this petition specifically relates to the issuing of a licence to an individual allowing for the importation and supply of an unlicensed cannabinoid-based product, which is currently unavailable in Jersey, as well as the UK.

Part (b) seeks to charge the Minister for Health and Social Services to review procedures for authorising patients to be prescribed Cannabis Sativa where all other legally licensed clinical options have been exhausted.

Background

Discretionary powers vested in the Minister for Health and Social Services grant the authority to issue a licence for the possession of cannabis for “research or other special purposes”.

Jersey legislation is identical to that of UK legislation in this matter.

While there is no legal definition of “special purpose”, the long standing interpretation of “special purpose” in the UK has been confined to industrial hemp production.

It is unlikely that “special purpose” was ever intended to cover medicinal use, as any substance which is acknowledged as having recognised medicinal benefit would be classified differently under misuse of drugs legislation, negating the requirement for the issuing of a special licence.

The broader and more fundamental question, therefore, is whether or not Bedrocan BV should be classified in the same way as, for example morphine, to allow for medicinal use.

This could, and would, only happen after consultation with the Misuse of Drugs Advisory Council, and it is not for the Minister for Health and Social Services to predetermine that a drug should be classified differently under the provisions of the Misuse of Drugs (Jersey) Law 1978.

Bedrocan is not currently a licensed product for medicinal use. It has not undergone the clinical trials, nor provided sufficient evidence of effectiveness and safety, to meet the criteria necessary for the granting of a licence by a national medicines regulator such as the Medicines and Healthcare Products Regulatory Agency in the UK.

Had Bedrocan been proven to have recognised medicinal use it would be classified as such, and it is not appropriate, therefore, to utilise the ‘special purpose’ clause.

In any event, an application for a licence would have to be based on clinical evidence, in an application made by a consultant, who is a recognised expert in the field of medicine for which the drug is being sought.

Issues

Bedrocan remains an unlicensed drug – and no licence has ever been granted to an individual for personal medicinal use in Jersey or the UK.

The petitioner is a named person supported by a States member who is seeking the granting of an individual licence for her to be professionally prescribed and supplied with the unlicensed Bedrocan BV products.

In this specific case, the petitioner has not exhausted all other possible licensed treatments for the condition.

Good clinical practice dictates that, where professional medical assessment of a patient's clinical condition dictates a course of action, or a treatment worthy of therapeutic trial, a licensed medicine should always be used in preference to an unlicensed one.

Bedrocan remains an unlicensed product across most parts of the globe, including the UK and Jersey, and no licence has ever been granted to an individual patient for personal medicinal use.

All applications that have been made in the UK to the Home Office for the granting of a licence for Bedrocan under discretionary powers have been rejected.

A decision on the suitability of a cannabinoid-based product for medicinal purposes should always be a clinical one, made by the appropriate professional consultant who is an expert in the field of medicine for which specialist treatment is being sought.

The procedures for managing a patient's treatment in these circumstances reflect those required for any medical condition, that is, referral by a G.P. or other health professional to an appropriate consultant to provide professional clinical diagnosis and appropriate recommended treatment.

It would be wholly inappropriate for the States to intervene in this professional process, creating a position where medical professionals were compromised in their diagnosis or determination of appropriate treatment.

Summary

There is no universally determined or agreed definition or advice that would warrant the granting of an individual licence for the medicinal use of Bedrocan, under the "special purposes", in these circumstances.

Even if the Minister were in a position where the granting of a licence was appropriate, he could not prescribe or insist on the prescription of Bedrocan, or any other licensed or unlicensed drug, in any particular case.

While the Law allows for the Minister for Health and Social Services to issue a licence for 'research and special purposes' it does not provide for the Minister to step into the shoes of a doctor and, in effect, take clinical decisions in respect of an individual case.

This decision will always rest, rightly, with the medical professionals in whom we have vested responsibility for clinical care and treatment because they have the knowledge and medical expertise to do so.

Licensed medicines should always be used before consideration is given as to whether an unlicensed or investigational product would be an appropriate option.

Bedrocan is an unlicensed and currently unproven cannabis-based product, which has not undergone sufficient clinical trials to support the effectiveness and/or safety of its use for medicinal purposes. It does not have NICE approval, nor has the Misuse of Drugs Advisory Council given any indication to date that Bedrocan should be licensed for medicinal purposes.

Until such time as that advice alters radically, I do not consider the authorisation of special licences for the individual use of Bedrocan, or other unlicensed cannabinoid-based products, for medicinal purposes to be an appropriate measure.

I cannot, therefore, support any part of Deputy M. Tadier of St. Brelade's proposition, and I would urge members to vote against both parts (a) and (b)