WRITTEN QUESTION TO H.M. ATTORNEY GENERAL BY DEPUTY H.L. JEUNE OF ST. JOHN, ST. LAWRENCE AND TRINITY QUESTION SUBMITTED ON TUESDAY 6th MAY 2025 ANSWER TO BE TABLED ON WEDNESDAY 14th MAY 2025

Ouestion

"Given that, in the UK, legal liability for unlicensed medicines rests with the prescribing clinician, will H.M. Attorney General explain how legal liability for the production and prescription of cannabis-based medicines is determined in Jersey; and will he advise whether Jersey's legislation provides an equivalent safeguard or alternative framework to that found in the UK?"

Answer

Jersey, in parity with the UK, does not have bespoke legislation governing liability arising out of the production and prescription of unlicenced medicines but relies instead on existing legal principles to act as a safeguard, primarily the private law civil action in the tort of negligence. The potential routes for liability in relation to those medicines will vary depending on the specific circumstances in play. I have however identified below the main routes under which liability for such products may arise.

Liability for production

There are licensing frameworks in place which regulate the production of Cannabis Based Products for Medicinal use ("CBPMs") specifically (pursuant to the Misuse of Drugs (Jersey) Law 1978) and more generally under the <u>Medicines (Jersey) Law 1995</u> ("the 1995 Law"). The Minister for Health and Social Services is responsible for authorising licences under these Laws and their associated Orders.

Licence holders are required under the Medicines (Standard Provisions for Licences and Certificates) (Jersey) Order 1997 and the Misuse of Drugs (General Provisions) (Jersey) Order 2009 ("the 2009 Order") to have appropriately qualified personnel to supervise the production of CBPMs and to ensure compliance with the principles and guidelines of Good Manufacturing Practice ("GMP"). GMP describes the minimum standard that a medicines manufacturer must meet; those principles are set out under European legislation (initially Commission Directive 2003/94/EC and now under Commission Directive 2017/1572) and include provisions relating to the consistency of the product produced and quality control.

The Minister has the power to revoke licences issued under these frameworks should concerns be raised. Furthermore, failure to meet GMP standards in the production of medicinal cannabis would prevent it from being classified as a CBPM and as such the product could not lawfully be sold or prescribed. A manufacturer who nevertheless placed such a product on the market would be at risk of criminal prosecution for offences under the 1978 Law and to civil law negligence claims for any harm caused to patients as a result.

Liability for prescription

CBPMs may be prescribed to patients as they are a Schedule 2 drug under the 2009 Order. Article 5 of the 2009 Order permits doctors, dentists, pharmacist independent prescribers and nurse independent prescribers to administer Schedule 2 drugs.

Most CBPMs are "unlicensed" medicines because they have not been granted a product licence in Jersey, or a marketing authorisation in the UK. The factors which the Minister must consider in determining whether a licence should be granted are detailed under Article 20 of the 1995 Law; these factors relate to the safety, efficacy, and quality of the medicinal product.

A healthcare professional, who is lawfully permitted to prescribe Schedule 2 medicines, may prescribe unlicensed CBPMs and oversee their use but this will be done at their own risk.

Prescribing and dispensing of unlicensed medicines exposes both the prescriber and the dispensing pharmacist to potential liability. Without a product licence (or marketing authorisation), there is no licence holder to take responsibility for any adverse reactions associated with the product's use, and this means any liability rests with the prescriber. Prescribers are accountable for all aspects of their prescribing decisions. They must ensure that their prescribing activity is within their sphere of competence and is safe and consistent with the clinical requirements of the patient.

The legislative framework does not give any immunity to prescribers against claims for suppliers of unlicensed medicines. This means that a prescriber could be liable for a personal injury claim if an individual suffers any harm which may have been caused by the negligent administration of the CBPM, or if the patient was not made fully aware of the possible risks involved in taking unlicenced medication.

Criminal Liability

Finally, as CBPMs are a controlled drug under the Misuse of Drugs (Jersey) Law 1978, anyone involved in the process from production to the individual who is prescribed CBPMs may be criminally liable if those medicines are shared, sold or otherwise used in a way that is not consistent with the legislative framework outlined above.