

POT LUCK: MARKETING CANNABIS BASED PRODUCTS FOR MEDICINAL USE IN THE UK

Following several high-profile cases advocating the medicinal benefits of cannabis, in late 2018 the UK government implemented changes to the classification scheduling of cannabis-based products for medicinal use ("CBPMs"). Consequently, it is now possible for businesses to manufacture, import, supply and distribute CBPMs in the UK under certain medical product regulatory regimes.

There are significant rewards for businesses that are able to establish themselves in the UK CBPM market. However, there will also be significant penalties and criminal sanctions for businesses that do not comply with the regulatory regimes governing the supply of medicinal products in the UK.?

Routes to the CBPM Market in the UK

Under the medicinal products licensing regime, there is a general prohibition on supplying unlicensed medicinal products in the UK. Accordingly, businesses can only market and distribute CBPMs that have been approved and licensed by the national medicines regulator (i.e. the Medicines and Healthcare products Regulatory Authority ("MHRA")) or (subject to Brexit) the European regulator (i.e. the European Medicines Agency ("EMA")) pursuant to the grant of a marketing authorisation. The process for obtaining marketing authorisation is neither fast or cheap, however, securing a marketing authorisation will enable a business to market its CBPM product to a wider market.

There are certain exemptions to the general prohibition (e.g. unlicensed "specials" exemption) that, in special clinical cases, may permit the supply of CBPMs in the UK without a marketing authorisation, subject to meeting certain criteria set by the relevant regulatory body. However the availability of those exemptions will cease over time as others develop and obtained licensed forms of CBPMs

Regardless of whether a business follows the licensed or unlicensed route to market, it will need to obtain several licences, certifications and approvals before it can take any action to put a CBPM on the UK market.

Licences

As a bare minimum, businesses will need to apply for and obtain licences from the UK licensing authorities to deal with and import CBPMs into the UK. Additional licences and certifications may also be needed depending on the planned activities of the business (e.g. manufacturing CBPMs in the UK; cultivating cannabis in the UK etc.).

Careful consideration will need to be given to how the business will operate on a day-to-day basis, particularly since CBPMs remain controlled drug products. This will include any logistics concerning the operation of the manufacturing/distribution site and identifying relevant responsible individuals for various compliance roles, in respect of handling controlled drugs together with the usual good manufacturing and distribution practices.

Next Steps

A new market has opened and is anticipated to be both lucrative and fast growing. Many businesses will be quick to try and claim their share. However, it will be those businesses that have taken the necessary pre-action advice and carefully considered the approvals process that will stand to profit from the supply of CBPMs. A long term strategy is needed for those who look to enter the CBPM market, recognising that the product licensing and regulatory regime will change in the near term.

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