

Medical cannabis licensing in Malta

2021



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A study published in 2018 by market intelligence and strategic consultancy firm Prohibition Partners, has forecasted that the European cannabis market will be valued €115.7 billion by 2028.

According to the same study, while patient numbers are currently below 100,000 across the region, their number is set to grow to over 30 million in the next decade. In 2018 Malta introduced a bill to legalize the use of medical marijuana and attract companies willing to produce high-grade medical cannabis for the European market.

Thanks to the expertise of its regulatory team, Grant Thornton can assist entities throughout the process necessary to be recognized as licensed operators in the medical cannabis field in Malta.

The process is broken down into two phases.

Phase one

Following the completion of Grant Thornton's on-boarding process, an application with Malta Enterprise is submitted, and an introductory meeting is set up to introduce the promoters and the project to Malta Enterprise officials.

Should the outcome be satisfactory, the application is compiled and submitted to Malta Enterprise. The said application is primarily comprised of a thorough due diligence process and the submission of a business plan together with the relevant application forms.

Following a satisfactory outcome, Malta Enterprise issue a Letter Of Intent (LOI). It is possible to apply with Malta Enterprise as a 'company-in-information' and effectively incorporate the company further to a successful outcome of the process. However, it is essential to choose the name under which the company will operate from the outset.



Phase two

Following the receipt of a LOI from Malta Enterprise, the promoters are required to apply for an authorisation with the Medicines Authority. There are several technical requirements which need to be satisfied, such as the following:

- License holder name indication;
- Appointment of a qualified person who needs to be a pharmacist registered with the Maltese Pharmacy Council and is resident in Malta;
- Evidence of the site (this would typically be the space granted by Malta Enterprise on the LOI);
- Import and export permits, where required (separate processes with customs authorities);
- Details on destruction and waste management;
- Awareness of police report filings in case of loss/theft;
- Compliance with all local laws including occupational health and safety, employment, environmental, sanitary and waste management, electrical safety, tax, and anti-money laundering legislation;
- Security measures and monitoring of the site;
- Where relevant (manufacturing), the site is required to be EU-GMP compliant;
- Further rules on cultivation (however, it should be noted that from experience on this kind of applications, the opportunity for cultivation is limited, mainly only for research and development purposes where it does not make up the main activity of the licensed activity).

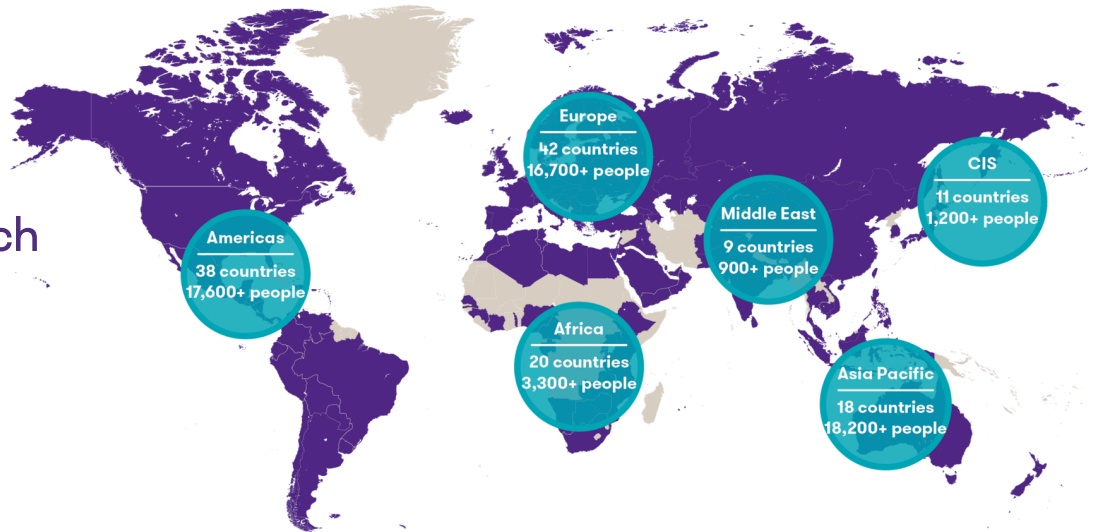
Promoters will also have to pass a thorough due diligence procedure by the Medicines Authority. A due diligence report in line with the rules established for this purpose needs to be submitted to the Medicines Authority.



Our role as your consultants

As your consultants for the whole process, part of our engagement will relate to the collation of all due diligence documents and carrying out of the necessary checks to compile a report which can then be presented to the respective authorities. It should be noted that the Medicines Authority may request further screening.

A global reach



We discover what is important to you and make it important to us

Our culture is built on a genuine interest in our clients – their challenges, growth ambitions and wider commercial context. You get the attention you deserve from approachable, senior professionals who ask the right questions, listen and provide real insight and a clear point of view.

The bottom line

- A relationship-led approach with more time and attention from partners and senior advisers
- A deeper understanding of your business for more meaningful advice and recommendations.

Agile and responsive service

Our size and structure creates advantages for you. We adopt a flatter structure, with shorter decision making chains, empowered teams and no complex chain of command. We have all the necessary processes and controls in a streamlined, efficient and responsive environment.

The bottom line

- A faster response when you need quick answers and clarity
- Anticipating the answers you will need before you ask.

Pragmatic solutions to help you improve and grow

Our teams bring ideas to the table, going beyond the technical issues to recommend ways to make your business better. We balance a desire to do what's best for you in the future with an experienced sense of what is going to help you now.

The bottom line

- Helping you think ahead and think more broadly
- Proactively identifying opportunities for improvement and growth

Collaborative teams with a different mindset

Our people are open, accessible and easy to work with. We work through the issues alongside you and challenge your ideas where necessary, whilst keeping an independent perspective. Our collaborative style also enables us to assemble teams across service lines, industries and geographies to tailor our capabilities to your requirements.

The bottom line

- Teams and solutions built around your needs not our structures
- A better working relationship with you and your team



Our distinctive client experience sets us apart



USD5.76bn
(2020 revenue)



58,000+
people



750+
offices



138
countries

Key contact

Related expert



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Wayne Pisani is the Partner responsible for the corporate and financial services team in Malta. He deals with a wide range of asset protection and cross-border regulatory and tax planning engagements for customers ranging from private clients, including family offices and high-net-worth individuals, to NASDAQ listed companies in various industry sectors. He conducts an active consulting practice on the legal and tax implications involved in the structuring of both local and international financial institutions, M&A and project finance transactions.

Wayne is the President of the Malta Institute of Financial Services Practitioners and a council member of the Malta Institute of Management. He is also a member of the International Fiscal Association, the International Bar Association and the Maltese Chamber of Advocates. He was admitted to the Bar in 2001 following a Bachelor of Arts Degree in Law and International Relations, and a Doctorate in legal studies from the University of Malta in 2001 after researching and submitting a thesis on "Merger control: a comparative study of regulatory systems for potential implementation into the Maltese legal system." Wayne also read for a Masters in Financial Services at the University of Malta, graduating in 2003 after submission of a thesis entitled "The Impact of Information Technology on Financial Services".

He is an active thought leader in the financial technology space, making regular contributions at fintech conferences, and has a passion for the security and technological aspects of distributed ledger technology.

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