

ITALY

I. Introduction

1. Identify the geographic scope and limits of your answers to the questions below.

The answers below refer to the Republic of Italy.

II. Legislation

2. Please provide links to applicable statutes and regulations.

The cultivation and the subsequent use of cannabis is regulated by the Presidential Decree No. 309 of 9 October 1990 (the “DPR 309/1990”) and by the Law No. 242 of 2 December 2016 (the “Law 242/2016”). As to the medical use of cannabis, reference has to be made also to the Ministerial Decree of 9 November 2015 of the Ministry of Health (the “Decree”).

The regulation is available (only in Italian) at the following links:

[DPR 309/1990](#)

[Law 242/2016](#)

[Decree](#)

A. Is there any pending legislation that could materially alter applicable statutes or regulations?

No.

B. Is there any proposed legislation that could materially alter applicable statutes or regulations?

Possibly yes. In the previous Government, the Interior Minister had declared its intention to enact a stricter regulation with respect to this matter. However, the members of new Government have shown some intention to take a more liberal approach. Therefore, also considering that some kind of intervention to clarify some gray areas is required by scholars, it is possible that the Government will address this topic in the upcoming months.

3. Are cannabis laws in your jurisdiction pretty well settled or are they constantly changing in material ways?

Despite the ongoing political debate, the laws *sub* 2. have been settled throughout the last few years. Moreover, in May 2019 the joint sessions of the Supreme Court of Cassation issued a judgment by which the Court explained how to correctly interpret and apply these provisions.

General information (e.g., governing bodies, licenses, import/export)

4. What governing body regulates/licenses or enforces activities that are allowed in your jurisdiction?

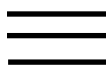
The Ministry of Health.

5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.

In general, according to the DPR 309/1990 no function is allowed, as the DPR defines hemp as a narcotic substance and therefore any activity in relation to it exposes the individual to criminal liability.

Nevertheless, art. 17 of the DPR 309/1990 sets forth an important exception to this rule: subjects will be allowed to carry out cultivation, production, import, export and other activities in relation to hemp, provided they request and obtain an authorization from the Ministry of Health pursuant to art. 27 of the same DPR (!).

¹ Please note that according to art. 17 (2) of the DPR 309/1990, drugstores do not need this authorization in order to purchase and sell narcotic or



According to art. 26 (2) of DPR 309/1990, the subjects who can obtain this authorization are universities and public labs for scientific, experimental or academic purposes.

In 2016, the Law 242/2016 changed the situation by allowing the cultivation of hemp for specific purposes only, i.e. the fight against climate change, soil consumption and the loss of biodiversity. Always for the same reasons the Law 242/2016 allows some industrial uses of hemp (for example, pursuant to art. 1 (3) letter c) of the Law 242/2016, hemp might be used for the production of food, cosmetics, biodegradable raw materials and semi-finished products for industries acting in different sectors). For these specific purposes, according to art. 2 of the Law 242/2016 farmers who cultivate hemp do not need the aforementioned authorization by the Ministry of Health, on the condition that the THC content of the cultivation remains below 0.2 %.

Moreover, pursuant to art. 4 of the Law 242/2016, the THC content of the cultivation needs to remain between 0.2% and 0.6 %. In case the THC percentage is higher, the competent authority might confiscate and destroy the concerned goods (please note that even if the percentage is higher, the liability of the farmer will be excluded if he respected all the provisions of law which regulate the way hemp has to be cultivated).

After 2016, although the main aim of the Law 242/2016 was to promote the agricultural uses of hemp for the aforementioned specific purposes, some companies interpreted this provision as a general liberalization of cannabis with a THC content below 0.6%. Therefore products with said THC content started being put on the market and being sold by small retail shops.

In 2019 the Supreme Court of Cassation in its Joint Sections intervened in order to clarify the interpretation of the relevant provisions (Judgment n. 30475/2019). According to the Supreme Court, all the functions that are not explicitly allowed by the Law 242/2016 remain under the scope of DPR 309/1990 and therefore they are not permitted. Further, these activities actually expose the individual executing them to criminal liability pursuant to art. 73 of the DPR 309/1990. In conclusion, according to the interpretation provided by Court of Cassation, the selling of cannabis turn out to be unlawful; nevertheless, the Supreme Court specified that the criminal liability of the seller will be excluded if the product does not actually have any narcotic or psychotropic effect, according to the so-called principle of “principio di offensività” (lit. “principle of offensiveness”).

The situation is therefore presently “unclear”, and press, business operators and scholars are asking the Government for an intervention for clarification purposes.

6. What sales or use is allowed in your jurisdiction? E.g., edibles, vaping, tinctures, food additives, etc.

As anticipated in the previous point, pursuant to art. 1 (3) letter c) and art. 2 (2) of the Law 242/2016, the cultivation of hemp may be aimed at obtaining food, cosmetics, semi-finished products (such as fiber, oils or fuels), organic material for bioengineering or bio-construction or it might also serve educational, demonstrative or research purposes carried out by public or private institutes. Moreover, the cultivation of hemp is permitted for medical use pursuant to the Ministerial Decree of 9 November 2015 of the Ministry of Health.

The use of hemp for recreational purposes debated, but the case-law seems somehow to admit products not having any narcotic or psychotropic effect.

A. Are the rules different for medical vs. adult recreational use?

Yes, in relation to the medical use of cannabis, higher percentages of THC are allowed.

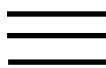
B. Are retail sales of any cannabis products restricted to specific retail channels? E.g., medical dispensaries, government-owned stores, etc.

The sale of cannabis products for medical use is allowed only through medical dispensaries.

With reference to the purposes set forth by Law 242/2016, the farmers who cultivate hemp can sell it without authorization on the condition that they respect the provisions of the same law.

Private retained hemp shops have become quite frequent, but the relevant legal status is uncertain.

psychotropic substances in the dose and form of medications.



C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located? Applicable to all cannabis products?

No, there are not.

7. What import and export is allowed in your jurisdiction?

A. Are there restrictions in relation to the countries of origin, i.e. which countries of origin are permitted?

No.

B. Please describe restrictions on the import of cannabis seeds.

The import of hemp and its derivatives in the EU is regulated by Regulation (Eu) No 1308/2013 of the European Parliament And of the Council and more specifically by art. 189. The regulation establishes that in order to be imported in the EU, the percentage of THC contained in cannabis seeds must be below 0.2%. This rule applies both to seeds used for planting and those used for different purposes, which can be imported only by subjects who are recognized by the member State.

Further, pursuant to art. 1 of the Ministerial Decree of 9 November 2015 of the Ministry of Health, the Ministry of Health has the authority to import and export plants and vegetal material containing cannabis.

8. Does your region distinguish between different types of cannabis products? (E.g., high or low concentrations of THC.)

Yes, it does.

A. If so, what distinctions exist?

The distinction refers to the percentage of THC contained in the hemp cultivation.

B. If so, briefly describe the differences.

Please refer to the answer *sub* 6.

C. Identify any related laws that should be considered when answering this question. Please refer to the following:

DPR 309/1990; Law 242/2016; Ministerial Decree of 9 November 2015 of the Ministry of Health; Council Directive 2002/53/EC.

9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?

No, there are not.

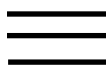
IV. Patients and prescriptions

10. What specific medical conditions, if any, are recognized for treatment with cannabis?

According to the Ministerial Decree of 9 November 2015 of the Ministry of Health, cannabis can be prescribed by doctors:

- for analgesic purposes to patients who suffer from illnesses which cause chronic pain and who show symptoms of nausea and vomit caused by chemo;
- for stimulating appetite in patients diagnosed with tumors, AIDS or anorexia nervosa;
- for hypotensive effect in glaucoma;
- for reducing involuntary movements of the body and of the face in patients diagnosed with Tourette syndrome.

Please note that for all the above mentioned purposes, cannabis can be prescribed only if other traditional treatments have shown to be ineffective.



11. Is there a licensed practitioner requirement in order to prescribe cannabis for medical purposes?

Yes, there is. Only a fully recognized practitioner can prescribe such medication.

12. Are there patient registration or cardholder requirements?

According to the Ministerial Decree of 9 November 2015 of the Ministry of Health, the “Istituto Superiore della Sanità” (lit. the Higher Health Institute) must keep a register in which all the information about patients prescribed with cannabis have to be reported. Therefore, the “Aziende Sanitarie Locali” (lit. the local health authorities), on behalf of the doctors who prescribe the medication, have to file the register with the patients’ personal information, the reasons why the medication was prescribed and the outcomes of the treatment.

V. Special requirements

13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?

Pursuant to art. 3 of the Law 242/2016, farmers must keep the relevant tags of the seeds they purchase for at least 12 months. For the same amount of time, farmers must also conserve the invoices of the purchase of the seeds.

14. Are special taxes imposed? On what and when?

No, there are not.

15. Are there any special rules or limitations that apply to the industry? E.g., banking, patent or trademark protection, labeling requirements.

No, there are not.

16. What is the legal status of access to financial services, including banking, merchant services, and cash handling?

There is no special regulation in access to financial services for subjects operating in cannabis sector.

17. Is data collected to determine the social or health impact of the rules in your jurisdictions? E.g.,

A. Impact on use by under age/minors.

B. Impact on beer, wine and spirit sales.

C. Tax revenue.

D. Impact on crime, including drug and alcohol addiction.

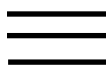
Not by any official source, apart from what already specified in question no. 14.

VI. Risks and enforcement

18. What are the most critical issues currently facing the industry in your jurisdiction?

The crucial issue the industry is facing in Italy is uncertainty, following the decision of the Supreme Court of Cassation previously mentioned *sub.* no. 6 in connection with the sale of products without any narcotic or psychotropic effect. Such uncertainty can expose to the risk of criminal prosecution and is likely discouraging several business operators from engaging in the market.

Furthermore the political debate on the issue is still ongoing and it is not sure if and when the new Government will enact an amendment to the current legislation.



19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.

A. Does enforcement differ based on quantity?

Yes it does. Pursuant to the DPR 309/1990, the possession of narcotic substances for personal use only does not result in the criminal liability of the possessor who will be punished with administrative sanctions (e.g., suspension of driving license for a period up to three years) ⁽²⁾. On the other hand, dealing with relevant quantities of such substances can result in the exposure of the dealer to criminal liability, if such substance has any psychotic effect.

B. Does enforcement differ based on product type?

Yes, as clarified above, it may differ based on the THC percentage contained in the product.

VII. Your practice and useful links

20. Tell us a little about your cannabis practice and how it interacts with other practices at your firm. Remember to include any recognition awards your firm has received in this practice area. How much experience does your firm have providing services to cannabis companies and how much interest does your firm have to grow its cannabis practice?

Due to legal uncertainty, the interest in the cannabis industry is still limited; therefore the recourse to legal consulting is still not very frequent.

21. Please provide links to any firm website, blogs, reputable trade publications, or attorneys that would help others understand the state of the law in your jurisdictions.

A. Are there any relevant trade organizations?

B. Are there any relevant lobbying organizations?

Yes, the “Consorzio Nazionale per la tutela della canapa” (lit. “National Consortium for the protection of hemp”), reachable at the following link:
<https://www.consorziotutelacanapa.it/>

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² Please consider that according to art. 75-bis of the DPR 309/1990, if by complying with art. 75 a risk for the public safety may occur (e.g. if the possessor has been previously found guilty for crimes against a person), it will be possible for the authority to apply criminal sanctions as well.