



Balneotherapy care facilities' legal operating framework

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Attributions and sources of norms

- There is a joint law by the State and the Regions in Italy to guarantee health protection (art. 117 of the Constitution).
- Legislative competence in the sector of mineral and thermal waters is attributed exclusively to the Regions and autonomous Provinces, of which these are a valuable part.
- The operation of a spa – and of a wellbeing centre connected to it – is regulated by a set of national and regional norms, some laws others regulations.

Main National Norms

- **Law No. 323 of October 2000**, containing “*The reordering of the thermal sector*”;
- **Royal Decree 28 September 1919/1924**, containing “*The regulation for the execution of Chapter IV of Law 16 July 1916, No, 1924, containing dispositions on mineral waters and thermal establishments, hydrotherapies and similar physical treatments*”;
- **Ministerial Decree 20 January 1927**, containing “*Instructions for the utilisation and consumption of mineral waters*” which regulates, among other things, the transport (Article 34), and requires that “... *pools in which many bathe at the same time must have an abundant supply continuously renewing the water*” (article 55);
- **Royal Decree 27 July 1934, No. 1265** (*Approval of the unified text of the health laws*) that, in article 99, paragraph 2, among the figures of the “auxiliary trades” of the health professions, when describing the qualified or authorised nurses, includes among this latter category the head attendants of the hydrotherapy establishments as well as masseurs/masseuses;
- **Article 6, letter t) of Law 23 December 1978, No. 833**, that requires that the Minister of Health issue a document recognizing the therapeutic value of the mineral water that a spa intends to use in its establishment.

Regional Regulations

- **Regional laws** that regulate the research and use of mineral and thermal waters;
- **Required authorisation and accreditation from the National Health Service**, contained in the specific agreements that Federterme has signed with the Ministry of Health and the Regions

Main National Laws – 1

“Article 1, Royal Decree 1924/19

“As found in Law 16 July 1916, No. 947, only those waters, whose special therapeutic or hygienic properties, whether by drinking or in other curative uses, are considered mineral waters.

The following are not mineral waters:

- *Ordinary potable water, commonly commercialised, carbonated waters and seltzer waters, created by treating potable water with carbon dioxide;*
- *Water prepared extemporarily for medical prescriptions;*
- *I fanghi (therapeutic muds)”.*

Main National Laws – 2

Article 14, Royal Decree 1924/19

“The following are considered:

a) thermal baths, those which use therapeutically,

1° mineral waters

2° muds, both natural or artificially prepared, molds or similar;

3° natural or artificial jets;

b) hydrotherapeutic establishments, those which use common water for therapeutic objectives;

c) establishments for physical cures and similar, those which use general or partial massages, kinetic therapy, mechanic therapy, radiotherapy, radium therapy, phototherapy, thermotherapy, electrotherapy, aero therapy, heliotherapy or the cures based on special regimes or diets or similar”.

Main National Laws – 3

Article 3, Law 323/00

“Thermal establishments

1. Thermal cures are provided in the establishments of thermal enterprises that:

a) are in compliance with the act of mineral concession or sub-concession or other valid juridical authorisation to exploit the mineral waters used;

b) use, for therapeutic ends, mineral and thermal waters, or muds, either natural or artificially prepared, molds or similar, steams or mists, natural or artificial jets, if the therapeutic properties of the waters used have been recognised as found in articles 6, letter t) of Law 23 December 1978, No. 833 and 119, paragraph 1, letter d) of legislative decree 31 March 1998 No. 112;

c) are in possession of a regional authorisation, issued as in article 43 of the Law 23 December 1978, No. 833;

d) meet the minimum structural, technological and organisational requirements defined in article 8, paragraph 4, of the legislative decree 30 December 1992, No. 502 with its successive modifications.”

Main National Laws – 4

Article 3, Law 323/00

- *2. The thermal establishments are able to provide, in appropriate and distinct environments, services and treatments carried out on the human body with the exclusive or main objective of maintaining this latter in perfect condition, improve it and protect its esthetic appearance, modifying it through the elimination or attenuation of cutaneous blemishes.*
- *3. Being understood that if the requirements in article 2, paragraph 2 are met esthetic centres can provide services found in article 2, paragraph 1, letter b).*
- *4. The regions and the autonomous provinces of Trento and Bolzano promote with suitable regulatory measures the health qualifications of the thermal establishments and the integration of these with the other health structures of their territories, in particular in the area of rehabilitation, keeping in mind the specific epidemiologic situation and health programme.*
- *5. Thermal cures are provided by the National Health Service, as set out in article 4, in the establishments of accredited thermal enterprises, as in article 8-quater of the Legislative Decree 30 December 1992, No. 502, introduced by article 8 of the Legislative Decree 19 June 1999, No. 229.” December 1992, No. 502 with successive modifications.*

Main National Laws - 5

Article 2, paragraph 1, Law 323/00

“Definitions

1. *In the present law the following terms are intended as below:*

- *a) thermal waters: natural mineral waters as defined by the Royal Decree 28 September 1919, No. 1924 with successive modifications, used for therapeutic ends;*
- *b) thermal cures: cures which use thermal waters or products derived from them, where their therapeutic efficacy has been recognised for overall health in the phases of prevention, in rehabilitation therapy of the pathologies indicated by the decree in article 4, paragraph 1, provided in thermal establishments defined as in letter d);*
- *c) pathologies: diseases indicated by the decree in article 4, paragraph 1, that can be prevented or cured, also for rehabilitative ends, with thermal cures;*
- *d) thermal establishments: the establishments identified as in article 3, as well as those annexed to hotels, thermal institutes or nursing homes which possess the authorisations required by current legislation for activities different from those regulated by the present law;*
- *e) thermal enterprises: those enterprises, defined in article 2555 of the Civil Code, or their respective branches, made up of one or more thermal establishments;*
- *f) thermal territories: territories of municipalities in which one or more concessions for exploiting mineral or thermal waters have been granted.”*

Main National Laws – 6

Article 2, paragraph 2, Law 323/00

“Definitions

- 2. *The terms “thermal baths”, “thermal”, “thermal water”, “thermal mud”, “hydrothermal”, “thermae”, “spa (salus per aquam)” are used exclusively with reference to circumstances with recognised therapeutic efficacy as set out in paragraph 1, letter b).”*
- **So Italian thermal baths can be considered a protected “brand”**

Main National Laws – 7

Article 9, paragraph 1, Law 323/00

“Professional profiles

1. The professional profiles of thermal operators who work exclusively in thermal establishments are regulated by paragraph 5 of article 3-octies of the Legislative Decree 30 December 1992, No. 502, introduced by article 3 of Legislative Decree 19 June 1999, No. 229.”

- **Note.** This article institutes the profile of the thermal operator, specifically a professional subject who carries out his/her activity in a thermal establishment and does not have a strictly medical role.
- The technical table which the Regions/Ministry of Health/Federterme have created for the approval of the professional figure of the thermal operator, on the base of an agreement is still not formalised but it is hoped that it soon will be.

Regional laws on the research, exploitation and use of mineral and thermal waters – 1

Looking at the contents in the individual regional laws is complex, though their systems and contents may be similar.

So I have decided to give some general comments pointing out the “common” properties found in the several provisions.

Regional laws on the research, culture and use of mineral and thermal waters - 2

The permission to exploit a reservoir is granted by a mining concession, issued by the Region, which usually lasts for a period of between 10 and 30 years. The period is related to the concessionaire's technical, economic and organisational capacity and the amount of investment it intends to make based on the programme presented when making its request.

The concession is issued successively to the issuing, by the Ministry of Health, of a decree recognizing the therapeutic value of the water.

Regional laws on the research, exploitation and use of mineral and thermal waters -3

Rights and obligations are indicated in the mining concession. Those that protect the resource are among the most important of these (e.g. the identification of zones of respect and preservation zones) and to the payment of the concession fee (surface area, quantitative or based on turnover).

Regional laws on the research, exploitation and use of mineral and thermal waters- 4

The revocation of a research permit or of a concession may be issued against a researcher/concessionaire that does not respect the measures contained in their research permission/concession or in a case required by law (e.g. bankruptcy).

Technical Direction

As regards an establishment's technical direction it is well to remember that a Health Director must be named (a doctor who should be knowledgeable in medical hydrology) and also a Mining Director (a mining engineer or mining technician, as required by the circumstances described in paragraphs 1 or 2 of article 27 of the Presidential Decree 9 April 1959, No. 128) these figures, however, need not to be hired as employees.

Accessing thermal cures – 1

- Every Italian registered with the National Health Service has the right to a free once a year cycle of thermal services for pathologies where these cures can help.
- To use thermal cures it is necessary that one's doctor (GP, pediatrician, specialist in a branch of medicine relative to the pathology which is to be cured) issue a prescription prepared on the standardised prescription form of the National Health Service.

Accessing thermal cures – 2

- The prescription must indicate the diagnoses, corresponding to a pathology that can benefit from a thermal cure:

Pathologies	Among which:		Type of thermal cure
Gastrointestinal pathologies	Gastric dyspepsia Biliary dyspepsia Simple chronic constipation		Hydro-mud bath therapy; Rectal shower
Vascular pathologies	Varicose veins Post-thrombophlebitic syndrome Lymphedema	Primitive insufficiency of veins Angiopathic dermatosis	Thermal baths; Vascular course
Dermatologic pathologies	Psoriasis Eczema Dermatitis	Dermatosis Acne Burn scars	Bathing therapies; Mud baths
Pathologies of the urinary tract	Stones of the urinary tract and their recurrence	Infections in the urinary tract	Hydropinic therapy or cure
Gynecological pathologies	Chronic, nonspecific and dystrophic vaginitis with persistent leucorrhea	Painful Sclerosis of the pelvic connective of a scarring and involutive nature	Vaginal washes; Bathing therapies; Mud “panty” therapies

Accessing thermal cures – 3

Pathologies	Among which:		Type of thermal cure
Rheumatic pathologies	Primary and secondary arthritis Extra-articular rheumatisms Dysmetabolic rheumatisms: gout and pseudo-gout		Mud therapy or Luto-therapy; Bathing therapy; Anthro-therapy; Hydropinic therapy or cure
ENT pathologies	Chronic inflammations of the respiratory tracts (rhinitis and rhino-sinusitis); Allergic rhinitis; Non-specific vasomotor rhinopathy; Atrophic rhinopathy	Chronic rhino-otitis; Secreting medium otitis; Tubal disorders; Rhinogenic deafness; Chronic phary-tonsillitis; Chronic adenoiditis; Chronic laryngitis	Nebulization; Inhalations; Aerosol; Humages or Exhalations; Nasal irrigations and micronized douches
Respiratory pathologies	Acute and chronic tracheobronchitis; Allergic pathologies of the laryngo-tracheo-bronchial regions;	Chronic bronchitis either simple or associated with an obstructive component	Aerosol; Humages; Nebulizations; Inhalations

Accessing thermal cures – 4

- When the patient is accepted, the health director of the Spa, or some other delegated medical person, fills in the relative clinical record, before a careful medical visit to ensure that there are no clinical counter-indications to the cures and to identify the quality, times and ways for their prescribed administration.

Regulations on partial payment by patients

- All Italian citizens between the ages of 6 and 65 years old can use thermal cures after paying a fixed fee of 50 Euros for an entire cycle of treatments (unless they are excused from payment).
- There are reliefs for particular categories of subjects
 - Patients who are partially excused and must pay a fixed fee of €3.10;
 - Patients who are totally excused (so-called protected categories) are treated free of charge.
- All those who undergo cures are asked to declare on the back of the prescription, on their own responsibility, that they have not made use in the current solar year of another cycle of thermal treatments paid for by the National Health Service, or that they have the right to treatments foreseen for those belonging to the protected categories.

Regulations in favour of injured workers – INAIL*

- *INAIL (National Insurance Institute for Workplace Injuries).
- In Italy all dependent workers, but also semi-dependent, must be insured in INAIL by their employer.
- INAIL insures not only against accidents at the workplace, but also diseases contracted at the workplace and professional diseases deriving from a specific type of work.
- Injured workers may use hydro-mud thermal cures paid for by INAIL, following a verification visit from a doctor of the Institute.
- Both health and economic services are provided. These consist of all travelling expenses of the patient to include if necessary an accompanier and both the patient's and accompanier's stays in a conventionalized hotel, as well as an indemnity to integrate the patient's direct salary.

Regulations in favour of injured workers – INAIL

- The services provided by INAIL are financed by the National Health Service and the worker is required by law to make partial payment.
- Workers who have had accidents or those affected by professional diseases, have a right to treatment during the period of total inability, those entitled to pensions for which the final revision has not expired; those sick with silicosis or asbestosis for unlimited periods.
- To obtain the necessary services one must present oneself at his/her local INAIL office. The INAIL doctor will then establish the cure, the appropriate type and length of the cure itself.

Regulations in favour of injured workers – INPS*

- All dependent and autonomous workers enrolled in INPS have a right to thermal treatments once they have reached the amount of contributions required.
- The services the agency may provide have the objective to delay the onset or remove a fair amount of the invalidity and they are limited to a single treatment for broncho-asmatic and rheumo-arthropic pathologies.
- ***INPS** (National Institute for Social Pensions).
- Through AGO (General Obligatory Insurance) INPS provides pension services.

Regulations in favour of injured workers – INPS 2

- The cost of thermal cures is paid by the National Health Service while that of the stay is paid by INPS.
- The insured worker is required to make partial payment as required by law. The expenses for the return trip to the spa are paid by the insured worker. The treatment is initiated after INPS has ascertained the existence of the required payments.
- Article 5 of the law reordering the thermal sector (No. 323/00) requires that the thermal regime applied to those insured by INPS be applied in the same way to those enrolled in other agencies/institutes which are substitutive of INPS and supply obligatory invalidity insurance, if they satisfy the same requirements asked of those applied to those enrolled in INPS.

Directive 2011/24/EU on the rights of patients relative to cross-border health assistance – 1

- Over the last ten years, the EU Court of Justice has issued sentences that confirm the right of patients to receive treatment outside the country in which they reside and under specific conditions obtain refunds, but the relative procedures are still today not totally clear.
- During 2012, the Court for the Patients' Rights received about 270 reports on the issue of foreign cures.
- More than one third of the citizens (36%) complained of a non- or delayed authorisation on the part of their local health care centre; a further 27% report excessive bureaucracy or a lack of information on procedures to be followed; 23% a refusal to authorise; 13% problems related to the refunding of expences. In some cases the citizens had to seek loans and financing to pay for their travelling expences or handle a late refund.

Directive 2011/24/EU on the rights of patients relative to cross-border health assistance – 2

- The **Directive 2011/24/EU on the rights of patients relative to cross-border health assistance** was introduced recently and came into force in all countries in the EU on the October 25th to resolve this situation (but not all countries have implemented it). It has laid a concrete base:
 - for the institution of a network of national contact points that furnish clear and accurate information regarding cross-border health assistance;
 - for the creation of a network whose objective is to favour the exchange of experiences among EU countries on how to supply patients with the best possible cures, e.g. using new technologies.
- The Directive also defines the elements to be included in medical prescriptions used by patients who move from one EU country to another (cross-border prescriptions).
- This is a circuit which potentially concerns 600 million Europeans living in the EU's 28 countries, 2 million doctors and 20 million nurses and thermal operators that will allow access to a “network” of structures for cross-border treatments in which European citizens can choose – following agreements between the respective national health systems and in regimes of reciprocity – where they would like to have their thermal cures.

Directive 2011/24/EU – its implementation in Italy

- The Italian government has received from Parliament the delegation to issue a law that implements the Directive. The issuance of this is foreseen by 4 December 2013, with funds of 121 million Euros.
- The realisation of a National Contact Point in the Ministry of Health is planned in the near future. Regional Contact points are also foreseen, and should be set up soon in Veneto, Liguria, Trento and Valle d'Aosta.
- Finally it is worthwhile remembering that through a rapid implementation of the Directive Italy will be able to exploit the opportunities that this new market offers, guaranteeing to the thermal sector of the country and thus to the excellences of which this can boast, a precious opportunity to grow that will have a positive economic-employment effect in the relative territories and constitute a new attraction for both traditional tourism and thermal wellbeing tourism.

SPAS



WHEN WITHOUT BORDERS?