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PALLIATIVE CARE AND PAIN THERAPY IN ITALY

In Italy the idea of pain therapy has progressed very slowly and laboriously because of a very restrictive law (Decree of the President of the Republic no. 309/1990) that assimilated the antalgic use of opioids with substance abuse. For quite some time there had been requests for a new law allowing opioids to be used for pain therapy, enabling a change in the attitude of doctors and of patients who needed to be taught that they could ask for treatment against pain.

According to the World Health Organization palliative care is the active and holistic treatment of patients whose disease does not respond to treatment. As is well known, the WHO defines health as a state of complete physical, mental and social well-being and not merely as the absence of disease or infirmity. This definition contains the premise for recognizing the need to improve quality of life where there is no cure.

Palliative care is concerned with improving the quality of life of patients who have a poor prognosis in the short term, while pain therapy is applied to patients who are not necessarily close to death but who suffer from chronic pain, to patients giving birth, after surgery and during invasive diagnostic procedures. In the latter case we speak about pain proper, in the former case it is more appropriate to speak about suffering.

In Italy palliative care, that initially included the concept of pain therapy, started to be organized during the eighties of the last century. The Italian Society for Palliative Care, the largest scientific society in this sector in Italy, was set up in 1986, while the Floriani Foundation that aims at spreading and applying palliative care, had been set up in 1977.

Recently, in the context of a greater sensitivity towards the issue of suffering and terminal conditions, people are beginning to expect that they should be able to live the final period of their lives in conditions in which their dignity as human beings is respected and without being left feeling abandoned.[1]

Also the teachings of the Roman Catholic Church have long since stated that palliative care and the use of pain-killers are absolutely acceptable as

[1] For more thorough information see *Una medicina per chi muore. Il cammino delle cure palliative in Italia*, ed. O. Corli (Roma: Città Nuova, 1988); Giorgio D i M o l a, *Cure palliative. Approccio multidisciplinare alle malattie inguaribili* (Milano: Masson, 1994).

expressed by Pope Pius XII, by the Catechism of the Catholic Church and in its *Declaration on Euthanasia*.[2]

Palliative care and pain therapy confirm the dignity of the person because they focus on the person rather than on the diagnostic-treatment aspects of the disease.[3]

In recent years there may be an answer to the expectations of Italian citizens. On 15th March 2010, Act no. 38 was passed.

Act no. 38/2010 is entitled *Provisions for Ensuring Access to Palliative Care and to Pain Therapy* and it embodies the expectations of the Council of Europe, the European Union and the documents of the World Health Organization, thus bringing Italy up to speed with other western countries.

It puts an end to a historic phase characterized by inertia, improvisation and the fragmentation of health policies on palliative care.

By acknowledging the subjective right of each citizen to have access to palliative care and to pain therapy, Act no. 38/2010 expressly defines some fundamental principles that are to be complied with: (1) protect the dignity and autonomy of the sick person avoiding all forms of discrimination; (2) protect and promote quality of life until its very end; (3) provide adequate health and social care for the sick person and for his/her family.

Act no. 38/2010 thus confirmed subjective entitlement to palliative care and pain therapy.

In actual fact, the Italian Professional Ethics Code for Physicians, issued in 2014,[4] explicitly attributes to physicians the task of not only providing treatment to heal patients, where possible, but also of relieving pain and accompanying patients until their death:[5] also the professional code of ethics for nurses contains rules on palliative care.

However the recent Act no. 38/2010 is something more because in the Italian legal system a code of professional ethics is not a source of ordinary law but merely a sub-regulatory source; not even case law nor the literature constitute sources of law; an ordinary Act instead gives this subjective right the characteristic of certainty. It can quite rightly be stated therefore that with

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[2] For a comment in Italian, see Salvatore C i p r e s s a, *Bioetica per amare la vita* (Bologna: Dehoniane, 2010), 148-51.

[3] See Adriana T u r r i z i a n i, "Cure palliative," in *Enciclopedia di bioetica e scienza giuridica*, ed. E. Sgreccia, A. Tarantino (Napoli: Edizioni Scientifiche Italiane, 2010), 776-82.

[4] See Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri, *Codice di deontologia medica 18 maggio 2014* (https://portale.fnomceo.it/fnomceo/ Codice+di+Deontologia-+Medica+2014.html?t=a&id=115184).

[5] See Gaetano A n z a n i, "Consenso ai trattamenti medici e scelte di fine vita," *Danno e Responsabilità* 2008, no. 10: 957-64.

the entry into force of Act no. 38/2010 palliative care and pain therapy have become rights to which patients are entitled.[6]

The right to palliative care and pain therapy is a right that users can claim from the public system, from doctors and healthcare workers.

As regards the first aspect, the legal literature configures the fundamental freedom rights both in the negative—in that they imply a duty for third parties to abstain from interfering with such rights—and in the positive—in that they imply the obligation to provide a service by third parties; the former constitutes the freedom 'from,' the latter the freedom 'to.' The right to palliative care and pain therapy therefore could be considered as a specification of the right to health and included in the group of claimable social rights, consisting in practice in claims addressed to the legal system and to the public system requiring that adequate pain relief[7] means be provided in the form of analgesics and broadly in existential and relational terms, that is to say it would be unjust to withhold pain relief medication from a patient without due reason.

As regards responsibilities, any episode of imprudence, laxity and of outright omission may be construed as a case of professional negligence.

One of the most pertinent aspects of this recent Act concerns the importance attributed to hospices. Encouragement for the setting up of hospices had been given in a previous act, Act no. 39/1999, which also allocated funds for this purpose; what was missing in Act no. 39/1999, however, was a truly functioning care delivery network of which they could be a part, so as to coordinate with home care. It must also be pointed out that the setting up of palliative care facilities, in accordance with the program defined by Act no. 39/1999, was not fully achieved because not all the hospices provided for exist and are actually in operation.

As regards pain therapy, the use of opioids, which are the painkillers that are most effective in relieving pain, has only recently and not yet completely been freed from the prejudice against these substances linked to the idea of crime, and also from the bias that these substances always cause tolerance and addiction.[8]

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[6] See Paola La Licata and Francesco Chiattelli, "Cure palliative e terapia del dolore diventano un diritto da assicurare ai malati," *Guida al Diritto* 2010, no. 15: 16-35.

[7] See Matteo Gulino, Gianluca Montanari Vergallo, Francesca Romana Correnti et al., "La nuova disciplina in tema di accesso alle cure palliative e alla terapia del dolore: il rapporto medico-paziente e la rilevanza socio-giuridica della sofferenza," *Zacchia* 84, no. 2-3 (2011): 191-210. See also Francesca Negri, "La nuova disciplina in tema di accesso alle cure palliative e alla terapia del dolore," *Sanità Pubblica e Privata* 2011, no. 3: 15-24.

[8] See Marco Filippini and Manuela Maria Campanelli, *Cronaca di una legge che ci difende dal dolore* (Milano: Il sole 24 ore, 2011), 8-9. For more information see also Cesare Bonezzi, *Liberi dal dolore. La sofferenza fisica e le nuove terapie per curarla* (Milano: Mondadori, 2002);

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For quite some time there had been requests for a new law allowing opioids to be used for pain therapy, enabling a change in the attitude of doctors and of patients who needed to be taught that they could ask for treatment against pain.

Many patients still express their fears about psychophysical addiction, the fear that there may be no other drugs that are more powerful than opioids when the pain increases, the fear of losing control. There are biases also among health workers: a first bias is the belief that the patient's life may be shortened. Indeed the opposite is true because where antalgic treatment is used properly it may actually extend life, since it is pain that deteriorates the quality of life and may lead to death. Another bias is that drugs like morphine should be restricted to extreme cases and should be used only when pain becomes unbearable; moreover, according to this bias, morphine should be used only at dosages that are low enough not to cause addiction.

In spite of these fears opioids continue to be of primary importance in the treatment of pain, especially in the terminally ill.

Among the data on the use of opioid drugs, Italy was and still is lagging behind other countries (even though there are countries, in particular the poorer countries, where consumption of opioids is even lower due to lack of availability), because pain is often considered to be a negligible aspect of treatment; vice versa, fighting pain becomes the primary goal when healing is no longer possible.

The use of analgesics has a function that goes beyond mere pain relief: there are studies, for instance, which recognize that an adequate control over pain improves pulmonary function.[10]

Up until 2001, D.P.R. no. 309/1990 envisaged a rather complicated protocol for access to opioid drugs such as to discourage doctors from prescribing them. The procedure was similar to that of other narcotic substances and consisted in using special prescription forms, valid for ten days and distributed by the Association of Physicians and Veterinarians, which allowed a single preparation or dosage for the treatment of at the most eight days, with heavy penalties if such conditions were not complied with.[11]

Giovanni D el M i s s i e r and Laura C o l a u t t i, "Terapia del dolore," *Medicina e morale* 2002, no. 2: 255-60; Steven D. W a l d m a n, *Il trattamento del dolore* (Roma: Verduci, 2000).

[9] See e.g. Consulta laica di Bioetica, "L'uso degli oppioidi nella terapia del dolore," *Bioetica* 8, no. 3 (2000), no. 3: 548-51.

[10] See Giovanni R u s s o, "Il malato terminale (cap. XXX)," in *Bioetica medica per medici e professionisti della sanità*, ed. G. Russo (Leumann: Elledici, 2009), 370-82.

[11] See F i l i p p i n i and C a m p a n e l l i, op. cit., 10.

Some improvements were introduced with Act no. 12 of 8 February 2001 that provided *Rules for Facilitating the Use of Opioid Analgesic Drugs in Pain Treatment*[12] that, alongside other sources such as the Decree of the Minister of Health of 24 May 2001[13] and Act no. 405 of 16 November 2001, established the following provisions:[14] (1) Annex III-bis of the amended DPR no. 309/1990 listed the drugs that could be used for pain therapy: buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone. (2) Opioid drugs could be delivered to the home of the patient by health workers upon a statement signed by the General Practitioner, by the attending physician or by the hospital doctor who would have to specify the dosage and use for home care. (3) Prescriptions, written on special forms, could contain the prescription of two opioids for 30 days of treatment instead of 8 days. (4) Doctors could keep supplies of these drugs for urgent professional use by writing self-prescriptions, but were required to keep a copy of the prescriptions for two years and had to keep a register where they were to enter all the treatments made using such drugs. (5) Patients being discharged from hospital could directly receive from the health facility the drugs required for a first treatment cycle of 30 days paid for by the National Health Service.

The reform had an impact on the complex regulation of drug and substance trafficking without altering its basic underlying principles but simplifying the procedures providing access to drugs containing narcotics and opioids for specific therapeutic, and hence legal, purposes.[15] The changes introduced by the reform concerned specifically the prescribing, administration and sale of narcotic substances for therapeutic use. The boundary between legal and illegal use in the context of the instances provided for by the law was the notion of 'therapeutic' use of the narcotic substances.

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[12] A positive comment on this law is provided by Dino Amadori (see Dino A m a d o r i, "Finalmente è più facile prescrivere gli oppiacei," *Rivista Italiana di Cure Palliative* 3, no. 2 (2001): 114-9). Positive comments are made also by Giovanni Del Missier and Laura Colautti (see D e l M i s s i e r and C o l a u t t i, op. cit., 255-60), according to whom the regulation was aimed at facilitating a disinterested solidarity towards the patient. A more critical view of the Act is provided by Luca Benci (see Luca B e n c i,"La nuova legge: molte luci e qualche ombra," *Janus* 2001, no. 1: 39-43. See also Giuseppe A m a t o, "Commento alla L. 8 febbraio 2001 n. 12, norme per agevolare l'impiego dei farmaci analgesici oppiacei nella terapia del dolore. Con uno snellimento delle norme formali evitata l'applicazione distorta delle sanzioni," *Guida al Diritto* 2001, no. 8: 14-29; Cristina C e c c a r e l l i, Silvia R e n z i, Carlo M a r i n a i, "L'utilizzo degli oppioidi nella terapia del dolore dopo la L. n. 12 del 2001," *Rassegna Giuridica Farmaceutica* 2004, no. 79: 6-32; Giuseppe A m a t o, "Ancora sulla somministrazione di sostanze stupefacenti da parte del medico", *Cassazione Penale* 2005, no. 6: 2101-6.

[13] This decree approved a new prescription form for the drugs listed in Act no. 12/2001.

[14] See F i l i p p i n i and C a m p a n e l l i, op. cit., 11-2.

[15] See Daniela T r e n t a c a p i l l i, "Norma per agevolare l'impiego dei farmaci analgesici oppiacei nella terapia del dolore," *Legislazione Penale* 2002, no. 3: 563-9.

Hence it was not illegal for a doctor to prescribe narcotic or psychotropic substances after making a diagnosis of organic or functional disorder; the same therapeutic purpose held also in the case where, faced with a severe illness, the doctor prescribed these substances to alleviate suffering: the malice indicated in the law was excluded by the fact that the substance was prescribed for therapeutic, and hence legal, purposes.[16]

In any case the new Act basically introduced two novelties: identification of the drugs to be used as painkillers listed in Annex III-bis attached to the rules, and streamlining the prescription requirements for the drugs listed in the Annex (along with a simplification of controls, lighter penalties for pharmacists, new rules on ledger management and a new momentum for home care).

The abovementioned provisions were the expression of the legislative intention of promoting a closer cooperation among health institutions, patients and individuals involved at various levels, also in the framework of the creation of an integrated network of services for terminal patients.[17]

Some authors complained about the fact that light drugs, like *Cannabis indica*, which according to some research findings are effective in alleviating the pain of patients suffering from severe disorders and in lessening symptoms of enfeeblement, were not included among these substances.[18]

Things were made easier by the subsequent Decree of the Ministry of Health (4 April 2003)[19] which introduced a new special prescription form where the physician would enter the dosage, posology and number of boxes using numbers and the normal abbreviations and it also eliminated the obligation of indicating the residence of the patient and the need for the prescriber to keep a copy of the prescription for six months.[20]

Law Decree no. 272 of 30 December 2005 and the relevant conversion Act no. 49 of 21 February 2006 listed narcotic drugs in two tables, which are included in the Consolidated Text on narcotics:[21] irrespective of the distinction

[16] See Francesco P a n a r e l l o, *Terapia del dolore e questione eutanasia* (Soveria Mannelli: Rubbettino, 2001), 85.

[17] See ibid., 81-4.

[18] See ibid., 85.

[19] For a more thorough comment on Act no. 12/2001, updated to include the amendments introduced by M.D. 24-05-2001 and 04-04-2003, see Alberto A n d r a n i, "Norme per la prescrizione degli analgesici oppioidi nella terapia del dolore," in *Cure palliative in medicina generale*, edited by Maurizio Cancian and Pierangelo Lora Aprile (Pisa: Pacini, 2004), 105-9. See also Maria Cristina T i r a l t i, Luana P e r i o l i, Valeria A m b r o g i et al., "Aspetti normativi della ricetta medica," *Rassegna di Diritto Farmaceutico* 35, no. 1 (2004): 7-18; Massimiliano M e l i and Maria G e r r a t a n a, "L'attuale normativa inerente l'impiego dei farmaci analgesici oppiacei nella terapia del dolore," *Difesa Sociale* 85, no. 3-4(2006): 115-26.

[20] See F i l i p p i n i and C a m p a n e l l i, op. cit., 19.

[21] See ibid., 51.

between narcotic and psychotropic drugs, Table I includes the substances that have an addictive power and that may be subject to improper use; Table II includes the substances that have a pharmacological action (that may also contain substances indicated in Table I), and hence are used in treatment according to a sub-classification into five sections (A, B, C, D, E) that takes into account the decreasing capacity of inducing abuse.[22] This same law also envisaged a new prescription form to be approved with an ad hoc decree (Ministerial Decree of 10 March 2006) that would replace existing prescription forms.

The drugs listed in Section A can be prescribed by using a special ministerial prescription form: this section includes the drugs listed in Annex III-bis which includes ten drugs having a strong analgesic power (buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone) that are the ones mostly widely used in pain therapy. The drugs listed in sections B, C and D can be prescribed with a prescription to be renewed each time and that is retained by the pharmacist. The drugs included in Section E can be prescribed with a normal prescription form.

The Ministerial Decree of 18 April 2007 marked a further step forward in facilitating access to treatment. Indeed, it clarified that opioids could be used to treat severe pain irrespective of the type of disease; it further simplified the prescription of medicinal products containing the combination of codeine and paracetamol, and pharmacists were given final indications on the prescriptions required for galenical preparations. The same decree included, in Table II, Section B of narcotic and psychotropic substances, two drugs deriving from cannabis plus a chemical cannabinoid, whereas today, as a result of M.D. of 23 January 2013, the whole class of medicinal products of plant origin based on cannabis (substances and plant preparations, including extracts and tinctures) is included in Table II, section B.

In compliance with the Schengen Agreement, the Ministerial Decree of 16th November 2007, *Rules on the Possession and Transportation of Narcotic and Psychotropic Drugs by Individuals Going Abroad and Individuals Arriving on Italian Soil*, approved the certificate justifying the possession of narcotic substances listed in Table II for Italian citizens who are undergoing treatment and need to go abroad.

With the Ministerial Decree of 21 December 2007 oxycodone was entered into Table II, Section D of narcotic or psychotropic substances, thus making it easier for it to be described and dispensed.[23]

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[22] For a comment to the Act of 21 February 2006, no. 49 see Carlo Alberto Z a i n a, *La nuova disciplina penale delle sostanze stupefacenti* (Santarcangelo di Romagna: Maggioli, 2006).

[23] For the measures adopted after Act 12/2001, see Viviana F e l i c e t t i, Roberta G a r e r i, Elisabetta C a p o m o l l a et al., "Terapia del dolore: uno sguardo al cammino compiuto dalla Legge 12/01 ad oggi," *Rivista Italiana di Cure Palliative* 11, no. 1 (2009): 30-33.

A further step towards the current dispensing pattern of these drugs were the Ministerial Ordinances of 2009 dated 16 June, 2 July and 8 October.

With the first of these ordinances, many of the opioids in Annex III-bis, formerly listed in Section A of Table II, were included also in Section D, with the consequence that they could be prescribed using the normal medical prescription pads or using the prescription forms of the National Health Service. The second ordinance laid down the obligation for pharmacists to write down the identity data of the purchaser with a view to avoiding abuse, whereas with the third ordinance the latter obligation was restricted only to some substances.[24]

Act no. 38/2010 amended article 14 of D.P.R. 309/1990 and introduced a further criterion for drawing up the tables, making it possible to include in Table II, Section D some medicinal compounds used in pain therapy listed in Annex III-bis, restricted to pharmaceutical forms other than the parenteral form. The Tables were modified by the Ministerial Decree of 31 March 2010 that reinstated the same regulatory framework produced by the temporary application of the Ordinance of 16 June 2009. Later, with M.D. of 7 May 2010 tapendalol was added to Section A, while with M.D. of 31 March 2011 the same substance was added to Section D and to Annexe III-bis.

The prescription form of the National Health Service can be used for prescribing the drugs indicated in Annex III-bis that are listed in Table II Section A, if prescribed for pain therapy; moreover this form can be used to prescribe the injectable version of the drugs listed in Annex III-bis and repositioned in Table II Section D.

Private non-reimbursable prescription forms can be used to prescribe the drugs in section D but not those in Section A.

The special prescription pad is compulsory for prescribing the drugs listed in Section A (including some of those indicated in Annex III-bis) for treatments other than pain therapy.

In all these cases the prescriptions have to be written out for each subsequent purchase. The prescription form of the National Health Service must contain the TDL code (pain therapy) in order to qualify for exemption from partial payment;[25] in addition, the prescription of the drugs must indicate the dosage and refer to treatment for thirty days at the most.

Also private prescription forms must include the indication of *pain therapy* in order to distinguish them from prescriptions for drug addiction recovery and are subject to the same thirty-day limit and to the indication of dosage.

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[24] See F i l i p p i n i and C a m p a n e l l i, op. cit., 52-3.

[25] As early as 2004 Minister Girolamo Sirchia had made compounds and combinations of compounds for pain therapy totally reimbursable (see ibid., 25).

In the case of dispensing the drugs listed in Table II Section D, after 15 June 2009 and for the drugs in Table II Section A, pharmacists have the obligation of writing down the name, surname and address from an identity paper of the purchaser and must keep it for two years.

The complex procedure that pharmacists had to follow to get opioid supplies is abolished and therefore pharmacists may now order opioids via the internet as is done with all other drugs.

Moreover, the pharmacist has the possibility of adapting the prescription at the time of dispensing; that is to say he may give the user a number of boxes required to cover the thirty days of therapy even though the dosages contained in the commercialised boxes could in theory exceed thirty days. In the same way dispensing may be divided up and hence restricted to thirty days where for instance the prescription envisages a longer period of time.[26]

As envisaged by the Decree of the President of the Republic no. 309/1990, these drugs may be written out also by veterinarians to pet owners.

Progress in pain therapy has been finally made possible also in Italy thanks to Act no. 38/2010 whose innovations undoubtedly deserve to be looked upon positively.

When a carefully developed pain treatment plan is coupled with an attitude of listening, of welcoming and close presence, in most cases patients calm down and pain disappears.[27]

Besides the changes we have just mentioned, Act no. 38/2010 has other particularly significant points with regard to palliative care and pain therapy: the structuring of actual care networks (with a painstaking definition of the powers of the State and those of the Regions) the promotion of information campaigns to raise awareness about the issue, a more pertinent training for physicians and other health professionals.

Pain therapy has been introduced in the plans of the National Health Service which also envisages the establishment of networks of functional and integrated units for pain therapy activities delivered in different healthcare settings with the aim of improving the quality of life of people coping with pain irrespective of the etiopathogenesis of their illness, thus reducing the degree of disability and encouraging reintegration into the social and employment context.

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[26] See ibid., 103-6. See also Marisa Dal Zotto, Elisabetta Franceschinis, Luigi Bugada et al., "Legge n. 38 del 15 marzo 2010 recante disposizioni sulle cure palliative e sulla terapia del dolore: le ricadute professionali per il farmacista nella gestione dei medicinali stupefacenti," *Sanità Pubblica e Privata* 2011, no. 1: 5-26.

[27] See Patrick Verspieren, *Eutanasia? Dall'accanimento terapeutico all'accompagnamento ai morenti* (Cinisello Balsamo: Paoline, 1985), 110.

The network is structured into three levels and its points of access are general practitioners coordinated in combined working groups at community level based on collective agreements. These doctors have the task of taking care of the simpler cases of diagnosis and treatment and where necessary of referring the patient to specific centres (in a system of spokes and hubs).

The second level is represented by the office-based pain treatment programs (spokes) to which patients with average severity are referred for specialized examinations and for the definition of a pain treatment plan.

The third level includes the pain therapy hospital units (hubs), which are highly specialized facilities: difficult patients who have responded to treatment at the previous levels, and who therefore need highly specialized investigations and complex and invasive treatment (often long-term opioid treatment), are referred to these facilities. The hubs may also be given the task of monitoring technological innovations and complex treatment processes. Both the hubs and the spokes should be distributed in proportion to the population.

The organizational provisions contained in Act no. 38/2010 contribute to putting into practice the right to pain relief, even though there is a long way to go before we defeat pain, if ever at all, to the benefit of the person involved and for the enhancement of human dignity.