

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.⁹

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 Del 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 2001¹³ 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.

¹² A positive comment on this law is provided by Dino Amadori (see Dino Amadori, “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 Del Missier and Colautti, 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 Benci, “La nuova legge: molte luci e qualche ombra,” *Janus* 2001, no. 1: 39-43). See also Giuseppe Amato, “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 Ceccarelli, Silvia Renzi, Carlo Marini, “L’utilizzo degli oppioidi nella terapia del dolore dopo la L. n. 12 del 2001,” *Rassegna Giuridica Farmaceutica* 2004, no. 79: 6-32; Giuseppe Amato, “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 Filippini and Campanelli, op. cit., 11-2.

¹⁵ See Daniela Trentacapilli, “Norma per agevolare l’impiego dei farmaci analgesici oppiacei nella terapia del dolore,” *Legislazione Penale* 2002, no. 3: 563-9.