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ORIGINAL ARTICLES AND REVIEWS

Evolution of Italian laws banning trafficking, use and abuse of psychotropic drugs

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Abstract
The penalty system implemented by Italian law still represents a barrier against psychoactive drugs and drug addiction, especially at a time when the age of first consumption has considerably dropped. Presidential Decree n. 309 of October 9, 1990 entitled "Consolidation of the laws governing drugs and psychotropic substances, the prevention, treatment and rehabilitation of drug addicts", and referred to as Presidential Decree 309/90, is the reference text for the cultivation, production, trade and use of narcotics and other psychoactive substances in Italy. The Presidential Decree has its origins in the now-forgotten law of December 22, 1975, n. 685, amended by law 162/90, which provided a draft of the current Presidential Decree 309/90. The current text has been amended numerous times over the years.

Key words
- Presidential Decree 309/90
- psychoactive drug
- NPS
- legislative evolution
- Italy

INTRODUCTION

In ancient times, there was no moral problem regarding the use of psychoactive substances, as they represented a fundamental part of the relationship to the Gods, a link with medicine, and a spiritual connection with the body. Psychoactive substances were closely linked to the religious experience. They were mainly used as an entheogenic agent during rituals of vision and communication with the divine: peyote ("bread of the gods") in Mexico, ayahuasca ("liana of spirits") in the Amazon and Central America, iboga ("miraculous plant" or "tree of knowledge") in West Africa, kawa ("bitter, pungent, sour drink") in the South Pacific, and cannabis in the East. Drugs were also used by philosophers, for their stimulant and exhilarating properties. The ancient Greeks used them to cheer up their banquets (hemp, henbane, opium, mandrake). In the *Odyssey* of Homer, the author tells that Helen gave wine mixed with opium to Telemachus, the son of Ulysses, to alleviate his pain. Even the ancient Romans used psychoactive substances. With the development of the Christian religion, drugs started being regarded as "evil", and their use, either for medical or religious purpose, was severely punished. With the discovery of the New World, coca and tobacco were imported into Europe from Americas. In Europe, the development of scientific disciplines such as chemistry, pharmacology and medicine, restored the status of psychoactive drugs as active ingredients or excipients of medicines. In the second half of the 19th century, the use of drugs in Europe, either for recreative or medical use, spread considerably. Opium was used in pharmacies, even for children, due to its relaxing properties. Cocaine was preferred by intellectuals because it was regarded as a substance capable of amplifying critical and creative thoughts. In 1897, Bayer marketed heroin as a medicine to treat cough, respiratory problems and to fight morphine dependence. A year later, heroin was already a huge commercial success and was exported to more than twenty countries. In the 1930s, a number of "new psychoactive substances (NPS)", as they were so called at the time, were synthetized in laboratories and marketed. For instance, amphetamines were prescribed to treat depression and the excessive use of hypnotic medicines; they were also used in the military sphere because of their anorectic and psychostimulating properties. In 1943, the "lysergic acid diethylamide", or LSD, a hallucinogenic substance whose precursor can be extracted from the fungus ergot, was synthesised and was initially used as a stimulant in psychotherapy and to treat alcohol addiction. This review decribes for the first time the evolution of the National legislation on psychoactive substances since the first laws at the beginning of 20th Century till the Presidential Decree 309 of 1990 and subsequent amendements.

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METHODOLOGY

A wide-ranging search of relevant scientific literature has been performed using multidisciplinary databases (Scopus, PubMed, PubMedCentral, Research Gate, Medline, Google Scholar) and in legal search engines (NORMATTIVA, Regulatory archive of the Ministry of Health) with the aim to gather all relevant laws regarding psychoactive substances banning that were published from 1920 until December 2019. The used search keys were: Presidential Decree 309/90, Psychoactive Drug, NPS, Legislative Evolution. The search was limited to English language and Italian language materials, and all articles have been independently revised for content by three of the authors to verify their relevance within the framework of the present review. Only the articles that were ultimately considered relevant by at least two of the paper authors have been chosen.

RESULTS

The Italian legislation has always considered the production and illicit trafficking of drugs a crime, adopting repressive measures and always more incisive sanctions on the basis of International Conventions. The drug legislation was initially inspired by the prohibitionist point of view, although part of the public opinion called for separate treatment of cannabis and its derivatives (so-called soft drugs), asking for their legalization. The first drug law of February 18, 1923, n. 396, was part of a political-social context radically different from now, and considered drug use as a "vice".

However, it provided for the punishability of the consumers only if their conduct threatened public order. Morphine, cocaine and other "poisonous substances that in small doses give narcotic action" were controlled, identified and included in a specific list [2]. The 1930 Rocco Code established a number of measures aiming at repressing the trade and use of illegal drugs and the facilitation of use [3]. The subsequent reform resulted in the decree-law n. 151 of January 15, 1934, which repealed the previous law and absorbed some of the provisions of the penal code [4]. This regulatory framework remained in force until the introduction of the law of October 22, 1954, n. 1041, "Law on Narcotics - Discipline of their production, trade and employment" (law n. 1041, www.gazzettaufficiale.it/eli/id/1954/11/12/054U1041/sg), which severely punished all possible conducts concerning the narcotics, including detention for personal use [5]. This law took into account the control of cultivation, production and trade of the generally defined "psychotropic drugs" with particular attention on opiates, and severely punished personal use outside medical prescription. The spread of psychoactive substances in Italy began at the end of the 1960s, and has reached great proportions over the following decade. Given the inadequacy of the legislation, which was characterized by a merely repressive approach to the problem, providing for the punishability of the consumer who was considered as a delinquent, a political intervention was asked to the civil society that also took into account the social and health aspects of the drug phenomenon.

Subsequently, the law "Disciplina degli stupefacenti e sostanze psicotrope. Prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza. (Regulation of narcotic drugs and psychotropic substances. Prevention, treatment and rehabilitation of the related states of drug addiction)" was introduced on December 12, 1975 [6] (law n. 685, www.gazzettaufficiale.it/eli/id/1975/12/30/075U0685/sg). For the first time, the law recognized the possibility of not punishing simple drug users for their own consumption. However, there was no precise definition of the concept of "small quantity", which was therefore left to the complete discretion of the judges. For this reason, the Court of Cassation dictated guidelines to reach consensus, defining the concept of "small quantity" of drug that encompassed the notion of drug addiction. Furthermore, to reach a sentence of acquittal or conviction, it was required that, the magistrate, through scientific investigations, should understand the number of drug doses in addition to the nature and composition of the substance. During the 1980s, the trend in drug use reached worrisome proportions, with a significant increase of drug-related fatalities involving drug overdoses, road accidents under the influence, the onset of drug-related diseases (AIDS, viral hepatitis) and the increase drug-related crime. During the 1990s, Italy and most European countries faced the increase and spread of psychoactive substances using law enforcement, prevention policies (training and education in schools) and treatment and social rehabilitation programs. The need to cope with the increase and diffusion of drugs brought about a new turning point in the evolution of Italian legislation, achieved by the with law n. 162 (Vassalli-Russo-Jervolino) [7] "Aggiornamento, modifiche ed integrazioni della legge 22 dicembre 1975, n. 685, recante disciplina degli stupefacenti e sostanze psicotrope, prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza. (Updating, modification and integration of law n. 685 of December 22, 1975, regulating narcotic drugs and psychotropic substances, prevention, treatment and rehabilitation of the relative states of drug addiction)" of June 26, 1990 (law n. 162, www.gazzettaufficiale.it/eli/id/1990/06/26/090G0197/sg) [7] which provided a draft of the current Presidential Decree 309/90 [1]. This law restored the sanctions against holders of small quantities for personal non-therapeutic use. As a legislative instrument of intervention, the regulations in force were collected in a special consolidated text, the Presidential Decree 309/90, on the subject of the discipline of narcotic drugs and psychotropic substances, prevention, treatment and rehabilitation of drug addicts. With the Presidential Decree 309/90, the laws n. 685 and n. 162 and the applicative decrees issued by the Ministry of Health were unified, in order to align themselves on the resolutions adopted by the Member States of the European Community.

PRESIDENTIAL DECREE N. 309 OF OCTOBER 9, 1990

The law of June 26, 1990 (n. 162) [7] introduced into the December 12, 1975 (law n. 685) [6] numerous modifications, suppressions, substitutions and insertions of articles and paragraphs. It was therefore necessary to reorganize the whole discipline through the elaboration

of a "single text", which was adopted with the Presidential Decree 309/90 [1]. Laws n. 685 and n. 162 [7] were thus unified with the implementing decrees issued by the Ministry of Health. Before April 1993 popular referendum, personal use was linked to the quantity of the substance used, which should not, however, exceed the "average daily dose". Art. 73 was based on the system of double track sanctions, which made a distinction between "soft drugs" and "hard drugs". These drugs were divided into six tables. Tables 1 and 3 listed the so-called hard drugs (e.g., ecstasy or coca leaves). Tables 1 and 4 listed the so-called soft drugs (e.g., cannabis and derivatives). Finally, Tables 5 and 6 included products used for therapeutic purposes and containing substances mentioned in Tables 1-4, for their potential for abuse and dependence (e.g., anxiolytics, antidepressants and psychostimulants).

The Presidential Decree n. 309 of October 9, 1990: "Testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope, prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza. (Consolidation of the laws governing drugs and psychotropic substances, the prevention, treatment and rehabilitation of drug addicts)", (www.gazzettaufficiale.it/eli/id/1990/10/31/090G0363/sg) [1] referred as Presidential Decree 309/90, came into force in 1990, concerning the legal discipline of narcotic drugs and psychotropic substances together with rules for the prevention, treatment and rehabilitation of the relative states of drug addiction. It was divided into 12 different parts:

- *Title I* - Authorities and schedules (articles 1-16)
- *Title II* - Authorization and permits (articles 17-25-bis)
- *Title III* - Provisions relative to the cultivation and production, manufacture, use and wholesaling of narcotic and psychotropic substances (articles 26-37)
- *Title IV* - Provisions distribution (articles 38-49)
- *Title V* - Import, export and transit (articles 50-59)
- *Title VI* - Documentation and custody (articles 60-68)
- *Title VII* - Specific provisions governing the substances listed in tables IV, V and VI (articles 69-71)
- *Title VIII* - Penalties for illicit activities (articles 72-103)
- *Title IX* - Information and educational measures (articles 104-112)
- *Title X* - Regional, provincial and local authorities' responsibilities. Services for drug addiction (articles 113-119)
- *Title XI* - Preventive, curative and rehabilitation measures (articles 120-126)
- *Title XII* - Final provisions (articles 127-136)

Annexes to the Single Text on Narcotic Drugs

Title I indicates and reserves the responsibility for guiding and promoting the general policy of control, prevention and intervention in the sector of the National Coordination Committee for Action against Drugs, and determines the general supervisory functions of the Ministry of Health and the Ministry of Internal Affairs, as well as the particular powers of the Regions. The surveillance and control activities of the Police Forces are then established, as well as the tasks of information and operational coordination of the Central Directorate for Anti-drug Services, a joint association under direct orders of the Ministry of Internal Affairs. Articles 13 and 14 indicate the criteria for establishing the 6 Tables containing the list of controlled substances ordered by potential hazard, on the basis of which the criminal and administrative norms (Title I-VIII) apply differentiated punitive sanctions. *Titles II, III, IV, V, VI and VII* examine all aspects of the cultivation, production, manufacture, distribution, use, import and transit of psychoactive drugs, laying down specific requirements for authorisation, documentation and communication of data and information. The evolution of the criminal law on psychoactive substances is detailed in *Title VIII* and deals specifically with the measures of "repression" of illicit activities related to psychoactive substances, regarding both the treatment applied to the consumer and the limits of the criminal relevance of the conduct of detention. *Titles IX, X and XI* constitute a very articulated text that can be considered as the guiding principle of the law to give great effectiveness to the prevention, treatment and reintegration. In this context, a provision operating in the fields of information, education, medical and social assistance has been established. The *annexes* consist of Tables. The first four Tables list all psychoactive drugs and psychotropic substances connected to the system of sanctions for illicit use and placed under International and National Control (Tables I and III major sanctions; Tables II and IV minor sanctions). The first four Tables also include preparations containing the substances listed in each of these Tables. The Table of Medicinal Products indicates the medicinal drugs, with particular reference to the prescriptions of the medicinal products for pain therapy and the medicinal products used in the course of treatment for the cessation of addictions, based on narcotic and psychotropic active substances of current therapeutic use for human or veterinary use. The Table of Medicinal Products is divided into five sections A, B, C, D and E. In these Tables medicinal drugs are distributed according to their potential for abuse. The Tables also indicate the dispensing regime. Medicinal drugs with simplified prescriptive procedures are included in Annex IIIa. The evolution of the criminal law on psychoactive substances, currently represented by the Presidential Decree 309/90, has mainly considered four aspects: the legal treatment of the simple drug consumer, the limits of criminal relevance concerning drug detention, the public intervention in prevention, treatment/rehabilitation and the inclusion of new psychoactive substances in the Tables of banned compounds. On the other hand, the regulatory system for the detection of psychoactive substances has remained substantially unchanged over time. This regulatory system for psychoactive substances is characterised by the absence of a general notion of "drug". This means that the drug is not considered in terms of its origin (vegetable or synthetic), consumption method (e.g., chewing, smoking, injection, oral intake) and ability to cause alterations in interpersonal relationships and with the environment. The difficulty found in the identification of a univocal notion has therefore induced the legislator to prefer the

"Tabular System". In fact, in the Presidential Decree, only the substances included in annex Tables of the Presidential Decree 309/90 are considered as "psychoactive substances". The Presidential Decree n. 309 of 1990 has been the first exhaustive act on the regulation of psychoactive substances traffick and use in Italy.

AMENDEMENTS OF THE PRESIDENTIAL DECREE 309/90 DURING THE YEARS

Referendum of 1993

A turning point came with Presidential Decree of June 5, 1993 "Abrogazione parziale, a seguito di referendum popolare, del testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope, prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza, approvato con decreto del Presidente della Repubblica 9 ottobre 1990, n. 309. (Partial repeal, following a popular referendum, of the consolidated text of the laws on the discipline of narcotic drugs and psychotropic substances, prevention, treatment and rehabilitation of the relative states of drug addiction, approved by Presidential Decree n. 309 of 9 October 1990)" (law n. 171, www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=1993-06-05&atto.codiceRedazionale=093G0238&elenco30giorni=false) [8], which amended 309/90. In particular, Article 72, paragraph 1, which contained the prohibition of personal use and any unauthorised use of drugs and psychotropic substances, was repealed. By repealing Article 75, paragraph 1, and Article 78 paragraph 1, letter b and c, the notion of dose limit ("average daily dose") was also abolished. The positive effects of 309/90 – i.e. a reduction in the number of drug-related deaths, an increase in the number of people entering community detoxification protocols, the seizure of ever greater quantities of drugs – were therefore hampered by the referendum promoted and won by the Radicals in 1993, as only the distribution of drugs remained illegal. Since the referendum, and until 2006, even the detention of large quantities of drugs was criminally irrelevant. In these terms, the jurisprudence had been oriented, considering acceptable the possession of tens of grams of heroin, and even the transfer aimed at "group consumption". The regulatory framework had become both lax and unnecessarily rigorous. Lax at the user/drug dealer interface: without proof of sale, there was no illegal limit for possession. Unnecessarily rigorous at the recovery: in several cases, the drug addict who completed his stay in prison could be reincarcerated, even for minor crimes and despite rehabilitation, thus frustrating the efforts for recovery.

Decree of September 23, 2004

With the implementation of European Commission Directive 2003/101/EC of November 3, 2003 [9], and the Decree of September 23, 2004 "Attuazione della direttiva 2003/101/CE del 3 novembre 2003 della Commissione europea, per quanto concerne la classificazione ed i valori di soglia di alcune sostanze soggette a controllo, con sostituzione degli allegati I e III al testo unico delle leggi sulla disciplina delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309, come modificato dal decreto legislativo 12 aprile 1996, n. 258, recante il recepimento della direttiva 92/109/CEE relativa alla fabbricazione e all'immissione in commercio di talune sostanze impiegate nella fabbricazione illecita di stupefacenti o di sostanze psicotrope. (Implementation of European Commission Directive 2003/101/EC of November 3, 2003, regarding the classification and threshold values of certain substances subject to control, replacing Annexes I and III of the consolidated text of the laws on the regulation of narcotic drugs and psychotropic substances, referred to in Presidential Decree n. 309 of October 9, 1990, as amended by Legislative Decree n. 258 of April 12, 1996, transposing Directive 92/109/EEC to the manufacture and the marketing of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)" (www.myttex.net/forum/attachment.php?aid=1590) [10], regarding the classification and threshold values of certain substances subject to control, Annexes I and III of the consolidated text of the laws governing narcotic drugs and psychotropic substances were replaced by the following: Category I (1-phenyl-2-propanone, N-acetylanthranilic acid, lsosafrol cis and trans, 3,4-methylenedioxyphenylpropan-2-one, piperonal, safrole, ephedrine, pseudoephedrine, norephedrine, ergomethrine, ergotamine and lysergic acid), Category II (acetic anhydride, phenylacetic acid, anthranilic acid, piperidine and potassium permanganate) and Category III (hydrochloric acid, sulfuric acid, toluene, ethyl ether, acetone and methyl ethyl ketone).

Law February 2, 2001 (n. 12) "Standards to facilitate the use of opioid analgesic drugs in the treatment of pain"

Further amendments followed with two important laws: law of February 8, 2001 (law n. 12, www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2001-06-16&atto.codiceRedazionale=001A6713&elenco30giorni=false) [11] entitled: "Norme per agevolare l'impiego dei farmaci analgesici oppiacei nella terapia del dolore – Indicazioni applicative. Rules to facilitate the use of opioid analgesic drugs in pain therapy – Application guidelines" and law of February 21, 2006 "Conversione in legge, con modificazioni del decreto-legge 30 dicembre 2005, n. 272, recante misure urgenti per garantire la sicurezza ed i finanziamenti per le prossime Olimpiadi invernali, nonché la funzionalità dell'Amministrazione dell'interno. Disposizioni per favorire il recupero di tossicodipendenti recidivi. (Conversion into law, with amendments to decree-law n. 272 of December 30, 2005, containing urgent measures to guarantee the safety and funding for the next Winter Olympics, as well as the functionality of the internal administration. Provisions to encourage the recovery of recidivist drug addicts)". For the first time, By law n. 12, by the more and more pressing requests from patient associations in terminal phase were received with the aim of facilitating prescription and administration the following active substances (Annex III-bis): buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone,

hydromorphone, methadone, morphine, oxychodone, oxymorphone, in pain treatments for patients suffering from severe pain due to neoplastic or degenerative pathology. The offences, in prescription and dispensation, were all decriminalized and penalties were reduced to administrative pecuniary sanctions.

Law February 21, 2006, (n. 49)

The deppest revision of 309/90 was brought with the law of February 21, 2006, (law n. 49 - www.gazzettaufficiale.it/eli/gu/2006/02/27/48/so/45/sg/pdf [12] "Conversione in legge, con modificazioni del decreto-legge 30 dicembre 2005, n. 272, recante misure urgenti per garantire la sicurezza ed i finanziamenti per le prossime Olimpiadi invernali, nonché la funzionalità dell'Amministrazione dell'interno. Disposizioni per favorire il recupero di tossicodipendenti recidivi. (Conversion into law, with amendments to decree-law n. 272 of December 30, 2005, containing urgent measures to guarantee the safety and funding for the next Winter Olympics, as well as the functionality of the internal administration. Provisions to encourage the recovery of recidivist drug addicts)", conversion of decree-law December 30, 2005 (n. 272) [13].

With the law n. 49, also known as Fini-Giovanardi, all psychoactive substances that did not find any therapeutic use were included in a single Table that did not discriminate "soft" and "hard" drugs for personal use, resulting in equal sanctions. The former six Tables were reduced to two, of which only the second, subdivided into sections A to E by dependence liability, was relevant from a therapeutic and legal point of view. The rigorous choice of equalisation had, however, been mitigated by the reduction of the minimum penalty and the existence of mitigating circumstances referred to in art. 73, paragraph 5. The new system of sanctions – administrative and criminal – aimed to combine prevention, repression and recovery, assuming that drug use is not an innocuous exercise of freedom, but an act of rejection of the most basic duties of the individual towards the different communities in which he lives. The punishment of drug possession was reintroduced and a boundary was established between detention, which represents an administrative offence, and detention, which constitutes a criminal offence. The boundary was no longer represented by the "small quantity", which was subjective and arbitrary, nor the "average daily dose", but an objective quantitative Table for substance: if the drug in possession exceeded a certain limit, criminal sanctions were applied; if the quantity was below that limit, administrative sanctions were applied (suspension of the driving licence, weapon licence, passport, residence permit for tourists, and administrative detention of the scooter in use). With the new law, the criminal sanctions were gradual. For users who had committed a minor crime, a completely new measure was introduced if the person did not want to go through rehabilitation and had already been granted a sentence suspension: instead being incarcerated and upon request, convicted people could do public utility work for the entire duration of the prison sentence. Confirming existing provisions, which were made more appropriate to the seriousness of the crimes, recovery was favored from the moment when pre-trial detention was ordered: detention could be avoided by going under house arrest and starting, under certain conditions, a therapeutic program. To have a better chance of undergoing therapy, the possibility of suspending the execution of the final prison sentence was widened: the limit of punishment allowing suspension was raised from 4 to 6 years of imprisonment, which allowed a larger number of drug addicts to go through rehabilitation. The reform also had a profound impact on the management of drugs. It was important for both the doctor and the pharmacist to replace the old "two copies" prescription with the "tracing" one, reserving the use of only one category of medicines (Table II, Section A) and a maximum lenght of 30 days. In order to limit illicit activities associated with therapeutic use, the new discipline provided a draft of a copy of the prescription, limited to section A, which the patient must hold as proof of legal possession of the drug preparation. Galenic preparations may then be prepared only with the narcotic active ingredients listed in Section B of Table II, and the validity of the galenic and renewable prescription was limited to 30 days. The extension of section E prescriptions could not exceed three times in the 30 days of validity. A vouchers-purchase bulletin is necessary for cumulative orders. Although official, this bulletin is not printed by the State Polygraph and can be downloaded and printed directly from the Ministry's website and coexists with the old official model bulletin, which can only be used for one substance or preparation. Like all laws, the discipline of narcotics also needed rules of application and interpretation. It has been clarified that the discharge from the register of substances and preparations for destruction can only be made when the pharmacist loses the material possession of narcotic drugs to no availing itself of the possible entrustment by the Local Healthcare Units after drawing up a special report (Ministerial Health Note May 31, 2006 N. D.G.F.D.M/VIII/P/I.8d.q/20116). It has also been made clear that the compilation, of the voucher-purchase bulletin can be carried out also by a pharmacist other than the holder or director, provided that it was authorized for this purpose by formal act (Ministerial Health Note May 20, 2008 N. 0019201-P- 20/05/2008 DGFDM). Finally, as far as the model of the entry and exit register is concerned, the Ministry has clarified that the number of pages can be different from 200. This clarification therefore allows for registers with less than 200 pages to be set up and, consequently, to replace them more frequently, thus being able to destroy the prescriptions downloaded two years after the last registration, with an obvious advantage for the confidentiality of personal data.

Ministerial Decree of April 18, 2007

Subsequently, Ministerial Decree of April 18, 2007 "Aggiornamento e completamento delle Tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope e relative composizioni medicinali, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309, e successive modificazioni ed integrazioni, recante

il testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope e di prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza". (Update and completion of the Tables in the Presidential Decree n. 309/90, www.trovanorme.salute.gov.it/norme/dettaglioAtto?completo=si&id=23064) [14], was amended by the decree of April 29, 2007. The prescription of opioid analgesic medicinal products (Annex III-bis) was no longer limited to the treatment of severe pain caused by neoplastic or degenerative pathology. Therefore, these medicinal products can be used for the therapy of the severe pain (postoperative, trauma...), regardless of the origin of the pain itself. New substances were also added to Table I: total opium alkaloids, beta-hydroxymethyl-3-fentanyl, buprenorphine, intermediate destromoramide, (+) - 1 - methyl - lysergic acid diethylamide, morphine methyl bromide and other morphine derivatives with {pentavalent nitrogen} including N-oxymorphine derivatives (such as N-oxycodeine). For the same decree, the following substances were also removed from Table I: ethylcyclidine and ethyl ester of 4-phenylpiperidin-4-carboxylic acid. In the same Table, the common name of messalina has also been replaced by the common name of mescaline. New substances were also added to Table II, section B: delta-9-tetrahydrocannabinol, trans-delta-9-tetrahydrocannabinol and nabilone, while tramadol and the compositions containing this substance were removed from section B and D of the same Table. Moreover, medicinal compositions for uses other than the injectable ones containing destropropoxyfen in association with other active ingredients were moved from section D to section E of Table II.

The Ordinances of the Vice-Minister Fazio (June 16 and July 2, 2009)

Additional ministerial intervention consisted of the Ministerial Ordinance of June 16, 2009 "Iscrizione temporanea di alcune composizioni medicinali nella Tabella II, sezione D, allegata al testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope e di prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza. (Temporary entry of certain medicinal compositions in Table II, Section D, attached to the consolidated text of laws on the regulation of narcotic drugs and psychotropic substances and on the prevention, treatment and rehabilitation of the relative states of drug addiction)" (www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2009-06-20&atto.codiceRedazionale=09A07142&elenco30giorni=false) [15] with substances such as opioids, certain pharmaceutical forms, to a limited extent, and authorized analgesic substances, were transferred from section A to section D of Table II (buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, oxycodone, morphine, oxymorphone). The measure, which was followed by another Ordinance on July 2, 2009 "Supplements to the Ordinance of 16 June 2009 on "Integrazioni all'ordinanza 16 giugno 2009, recante Iscrizione temporanea di alcune composizioni medicinali nella tabella II, sezione D allegata al testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope e di prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza. (Temporary entry of certain medicinal compositions in Table II, Section D attached to the consolidated text of laws on the discipline of narcotic drugs and psychotropic substances and on the prevention, treatment and rehabilitation of their states of drug addiction" (www.gazzettaufficiale.it/eli/id/2009/07/08/09A08111/sg) [16] involved the following practical effects for physicians and pharmacists:

- use of personal prescription of the doctor or the National Healthcare System;
- overcoming, without limits, of the dose for thirty days of treatment (except in the case of National Healthcare System prescription);
- deletion of input and output recording;
- the obligation to store psychoactive drugs in a closed locker no longer applies;
- purchase without filing the bulletin (in the sole case of purchase from a wholesaler);
- destruction of prescriptions retained after six months;

However, with the Ministerial Ordinance of July 2, 2009, the obligation to identify the purchaser in the case of personal prescription was introduced. The goal was to avoid the circulation of falsified prescriptions without possibility to trace the person responsible for the presentation. The obligation to send to the Local Healthcare Unit and the Order of Pharmacists, by the end of each month, a summary communication of the prescriptions sent privately (white prescription) in the previous month was also provided for.

Law March 15, 2010 (law n. 38) "Arrangements to ensure access to palliative care and pain therapy"

After a process that lasted almost two years, law of March 15, 2010 (law n. 38, www.gazzettaufficiale.it/gunewsletter/dettaglio.jsp?service=1&datagu=2010-03-19&task=dettaglio&numgu=65&redaz=010G0056&tmstp=1269600292070) [17], entitled "Disposizioni per garantire l'accesso alle cure palliative e alla terapia del dolore. (Provisions to ensure access to palliative care and pain therapy)", was published in the Official Gazette n. 65 of March 19, 2010. The law had a very strong impact on the prescription and dispensing of medicines used in pain therapy. The rules were contained in art. 10 entitled "Simplification of procedures for access to medicines used in pain therapy" and intervened significantly on various articles of Presidential Decree n. 309 of October 9, 1990, which regulates narcotic drugs and psychotropic substances. The following amendments were enforced on April 3, 2010.

Article 14 (Table). The amendment to Article 14 provided for the inclusion in Section D of Table II of all medicinal products containing substances listed in Annex III-bis to Presidential Decree 309/90, namely: buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, provided that they are not parenteral preparations. The Ministry of Health was forced to amend the Table because the provision of law could be fully implemented.

Article 25-bis (destruction). Article 25-bis greatly

simplified the procedures for the destruction of psychoactive substances. The destruction could be carried out by allowed private companies which had to provide a report to be transmitted to the Local Heathcare Unit by the Pharmacy Director.

Article 38 (vouchers). The amendment to art. 38 removed the requirement for a written request to purchase medicinal products from Sections D and E, when purchased from suppliers other than wholesalers. In essence, the obligation to complete the bulletin only remained for medicinal products belonging to sections A, B and C, in all procurement scenarios.

Articles 41 and 43 (receivers). Indication of the addressees of simplified forms for prescription analgesic medicinal products (art. 41 and 43) passed from patients affected by severe pain during pathology neoplastic or degenerative to that more generic and extensive of patients who had access to palliative care and pain therapy.

Article 43 (medical prescription book). Paragraph 4-bis Article 43 provided for the possibility of the prescription of medicinal products belonging to section A, to be on the health service's medical preascription book national. However, it was obvious that, if the doctor prescribed the medicine of section A not under National Healthcare System control, only the medical prescription book must be used to Ministerial tracing.

Article 45 (buyer's documents). With regard to the obligations of the pharmacist in the dispensation of Section A medicinal products (art. 45, 1st paragraph), it should be ensured that (the pharmacist) the identity of the purchaser and took note of the extremes of an identification document from transcribe on the prescription to the following forecast that noted on the prescription the first name, last name and contact details of the buyer's identification document.

Article 45 (excess therapy). The legislator wanted to overcome the following problem: the pharmacist still sent out the prescriptions that should prescribe a quantity which, in relationship to the indicated dosage, theoretically exceeded the maximum limit of 30-day therapy, where the surplus was due to the number of contained dosage units in the packages on the market. The pharmacist was also allowed to reduce the number of packages to fit in with the requirements of the 30 days of therapy, taking into account however, the previous forecast was present and communicating to the doctor.

Article 45 (fulfilments). Paragraph 6-bis, added to Article 45, concerned the pharmacist's obligations if presented with a prescription, so-called white, prescribing medicines which, according to the ordinance of 16 June 2009 and this law, have passed, and will pass, from section A to section D.

Article 45 (reduced delivery). For all prescribed medicinal products and belonging to Sections A to E, the possibility was provided for, on request of the patient, reduced delivery than the prescribed quantity by giving communication to the doctor, or but in any case by the end of the year. 30-day period of validity of the prescription and reporting on it the quantities delivered from time to time (Article 45, paragraph 10-bis).

Article 60 (logbook). The amendment to Article 60 reduced to two years the conservation period of the entry and exit register date of last registration. In this way, the conservation time of the prescriptions of sections A, B and C (two years) was brought into line with the conservation time of the register and, obviously, of all the accompanying documents (bulletins, vouchers, reports of destruction, theft, etc.). In addition, art. 60, as amended, provided that the number of pages could be different from two hundred and adequate to the amount of drugs that would normally taken over and sold.

Article 68 (decriminalizations). Finally, with the addition of paragraph 1-bis to art. 68, the irregularities found relating to breaches of the regulations on record keeping were decriminalised.

Sentence n. 32/2014 of the Constitutional Court

With decree-law of March 20, 2014 "Disposizioni urgenti in materia di disciplina degli stupefacenti e sostanze psicotrope, prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309, nonché di impiego di medicinali meno onerosi da parte del Servizio Sanitario Nazionale. (Urgent provisions concerning the regulation of narcotic drugs and psychotropic substances, prevention, treatment and rehabilitation of the relative states of drug addiction, as per Presidential Decree n. 309 of 9 October 1990, as well as the use of less onerous medicines by the National Healthcare Service)", law n. 36, (www.gazzettaufficiale.it/eli/id/2014/3/21/14G00047/sg) [18], several amendments were made to the Presidential Decree n. 309/90, following sentence of 2014, n. 32 (www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2014&numero=32) [19], of the Constitutional Court, which reinstated the distinction between "soft" and "hard" drugs. Compared to the original single Table of Drugs, the decree-law returned to four Tables (plus a Table of "Medicines"), and considered separately cannabis and its derivatives, which ended up in the Second Table. The second exception concerned the sanctions: as a result of the combined effect of the new decree and the ruling of the Constitutional Court, the penalty system of the law n. 162 was revised. In this concern the penalties for imprisonment in case of possession of significant cannabis quantities and the trafficking of cannabis and its derivatives were again significantly reduced.

Moreover, a new Table of medicinal products was established to allow complete continuity in the production, prescription, and distribution of psychoactive medicinal products, with particular reference to the prescriptions of pain therapy medicinal products and medicinal products used in the course of treatment for the cessation of addictions. The modalities of prescription and dispensing therefore remained unchanged for all therapies with psychoactive drugs; the modalities of management of the medicines by the operators of the pharmaceutical sector also remained unchanged.

Therapeutic use of cannabinoids in Italy

Ministerial Decree 98/2007 "Aggiornamento e completamento delle Tabelle contenenti l'indicazione

delle sostanze stupefacenti e psicotrope e relative composizioni medicinali, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309, e successive modificazioni ed integrazioni, recante il testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope e di prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza. (Update and completion of the Tables containing the indication of narcotic and psychotropic substances and related medicinal compositions" as per Presidential Decree n. 309 of 9 October 1990 and subsequent amendments and additions, containing the consolidated text of the laws on the regulation of narcotic drugs and psychotropic substances and on the prevention, treatment, rehabilitation of their states of drug dependence) (www.trovanorme.salute.gov.it/norme/dettaglioAtto?completo=si&id=23064) has recognized the therapeutic properties of delta-9-tetrahydrocannabinol (THC), the main active ingredient of cannabis, and two other analogs of synthetic origin (dronabinol and nabilone). These substances are listed in Table II section B (art. 2), which lists the substances that can be used in therapy and prescribed according to Article 72, paragraph 2, of the consolidated law 309/90.

With the Ministerial Decree n. 33 of 2013, an update of the Tables containing the indication of narcotic and psychoactive substances was made, inserting in Table II section B the "medicinal products of vegetable origin based on cannabis (herbal substances and preparations, including extracts and tinctures" (www.gazzettaufficiale.it/eli/id/2013/02/08/13A00942/sg).

To the present day, the current classification of cannabis and derivatives, is finally dictated by the law n. 79/2014 (www.gazzettaufficiale.it/eli/id/2014/05/20/14G00090/sg), which confirms the therapeutic function of the substances mentioned above and therefore their inclusion in Table II section B, now renamed "Table of Medicines". However, the law also classifies tetrahydrocannabinol (THC) and its analogues in Table I (most dangerous substances), and cannabis and its derivatives – oil, resin, leaves and inflorescences – in Table II (substances with a lower risk of addiction).

Production, distribution and use of medical cannabis

According to art. 26 of Presidential Decree 309/90 "(…) the cultivation of the plants included in Table I and II of art. 14 (…) is forbidden in the territory of the State", however "the Minister of Health can authorize university institutes and public laboratories with institutional research purposes, to cultivate the abovementioned plants for scientific, experimental or didactic purposes". Thanks to this exception, the Ministry of Health and the Ministry of Defence signed an agreement on September 18, 2014, under which the military chemical-pharmaceutical plant (SCFM) in Florence now carries out the operations of cultivation and manufacture of the active substance of plant origin based on cannabis. It also provides for the packaging and distribution, upon request of the Regions and Autonomous Provinces, to local pharmacies or hospital pharmacies for the preparation of magisterial preparations, to be dispensed on presentation of a non-repeatable prescription, in order to meet the needs of the assisted population. The active herbal substance is therefore supplied by the SCFM or can be found abroad, following a series of procedures regulated by the decree of February 11, 1997 entitled "Methods of importing specialty medicines registered abroad", which allows the importation of drugs not distributed in the Italian Health circuit.

The Ministerial Decree of November 9, 2015 "Functions of the State Agency for cannabis provided for in Articles 23 and 28 of the Single Convention on Narcotic Drugs of 1961, as amended in 1972" (www.gazzettaufficiale.it/eli/id/2015/11/30/15A08888/sg) has laid down more detailed provisions on the subject. Article 1 has identified the precise functions of the Ministry of Health as the State Agency for cannabis, which:

- authorises the cultivation of cannabis plants for use in the manufacture of herbal medicinal products based on cannabis;
- identifies the areas of use for such cultivation;
- imports, exports and distributes across the national territory, i.e. it authorises the import, export, wholesale distribution and maintenance of stocks of cannabis plants and material;
- provides for the determination of the production quotas of active substances of plant origin based on cannabis on the basis of the requests of the Regions and Autonomous Provinces and informs the International Narcotics Control Board (INCB) at the United Nations.

A technical annex to the Ministerial Decree has dealed with the most practical issues:

- the dosage of the medicinal product is determined, as well as the the mean of production and distribution to pharmacies;
- States that treatments with cannabis cannot be considered "a therapy in the strict sense of the word", but only to palliate the standard treatments when they have not produced the desired effects or have caused side effects that cannot be tolerated;
- the possible therapeutic uses of cannabis are exhaustively indicated for diseases involving spasticity and pain (multiple sclerosis, spinal cord injury); chronic pain; nausea and vomiting caused by chemotherapy, radiotherapy and HIV therapy; with appetite-stimulating effect in cachexia, anorexia, oncology or AIDS patients; with hypotensive effect in glaucoma; for reduction of involuntary bodily and facial movements in Tourette's syndrome);
- a phytosurveillance system will be set up, and therapeutic responses to cannabis will be monitored, thanks to reports made by health professionals to the Istituto Superiore di Sanità about any suspected adverse reactions following administration.

Currently, Italy allows the exclusive therapeutic use of cannabinoids in the form of magisterial preparations based on cannabis, i.e. galenic drugs (e.g., tinctures, infusions, oils, extracts) prepared by the pharmacist in his laboratory. The only drug of synthetic origin, based on cannabinoids, and authorised for trade by Italian Medicines Agency is Sativex, which can only be used in the symptomatic treatment of muscle spasms in patients

with multiple sclerosis. The latter is a class H drug, and can therefore be supplied at the expense of the NHS only in the hospital environment and dispensed through hospital pharmacies and the territorial system.

New Psychoactive Drugs (NPS)

All narcotic drugs and psychoactive substances are now listed in Tables I, II, III and IV, which account for the substances with strong addictive liability and potential for abuse in decreasing order; these Tables are amended whenever there is a need to introduce or remove a new substance or change its location. These Tables, linked to the system of sanctions for illicit use, list the narcotic and psychoactive substances placed under International and National control. The Table of medicinal products, itself divided into 5 sections (A, B, C, D, E), displays the medicinal products containing narcotic and psychotropic active substances and currently used for therapeutic purposes in human or veterinary medicine, and exemptions for doctors, pharmacists and operators in the pharmaceutical sector. In addition, Annex III-bis of the same decree contains the medicines used in pain therapies, which benefit from simplified prescriptive procedures, marked in the Tables with a double asterisk.

Since July 2007, by separate decrees of the Ministry of Health entitled "Update of the Tables containing the indication of narcotic and psychoactive substances, as per Presidential Decree n. 309/90, and subsequent amendments and additions". Many new psychoactive substances *(Table 1 of this article)*, have been included in Table I [20-56].

"Substances with an analogy" were also included in Table I, and include substances with similar chemical structure or effects to the substances already present in the same Table (2-amino-1-phenyl-1-propanone, indazol-3-carboxamide, indol-3-carboxamide, 3-benzoylindole, 3-phenylacetylindole, 3-(1-naphthoyl)indole). Bupropion and pyrovalerone have been excluded from Table I. In Table II, herbal medicinal products based

Table 1
New psychoactive substances included in Table I, Presidential Decree n. 309790, since 2007

Cathinones	Phenethylamines	Synthetic cannabinoids	New synthetic opioids
4-MEC	2C-E	XLR-11	Furanylfentanil
Ethylone	25H-NBOMe	5F-Apinaca	3-Phenylpropanoylfentanyl
Buphedrone	2C-H	5F-APP-Pica	4-Fluoroisobutyrfentanyl (4F-iBF)
Pentedrone	25E-NBOMe	5F-APP-Pinaca	Benzylfentanyl
Alpha-PVT	4Cl-iBF	5F-PB22	Benzoylfentanyl
4F-NEB	25B-NBF	AB-Chminaca	Carfentanyl
Alpha-PHP	25B-NBOH	AB-Fubinaca	Cyclopentylfentanyl
Alpha-PVP	DOC	ADB-Chminaca	Cyclopropylfentanyl
BK-2C-B	3,4-DMA NBOMe	ADB-Fubinaca	Benzodioxolefentanyl
Isopentedron	4-EA NBOMe	APP-Fubinaca	Methoxyacetylfentanyl
Methylone	HHMA	BB-22	Tetrahydrofuranylfentanyl (THF-F)
bk-MBDB	HMA	Cumil-5F-Pinaca	Tetramethylcyclopropanfentanyl
Amfepramone	HMMA	MDMB-Chmica	Thiophenefentanyl
3.4-Methylenedioxypyrovalerone (MDPV)	25B-NBOMe	CP 47,497	Butyrfentanil
Mephedrone	25C-NBOMe	CP 47.497-homologous C8	2-fluorofentanyl
	25I-NBOMe	AM-694	U-47700
	4-Methylamphetamine	JWH-250	Acryloylfentanyl
	4-fluoroamphetamine	JWH-122	3-Methylfentanyl
		JWH-018	3-Methylthiofentanyl
		JWH-073	Acetylfentanil
			Morphine-N-Oxide
			Ocfentanil
Benzofurans	**Arylcyclohexylamines**	**Tryptamines**	AH-7921
6-EAPB	Deschloro-N-ethyl-ketamine	5MeO-MIPT	MT-45
	3-MeO-2-Oxo-PCE	ETH-LAD	6-MAM
		5-MeO-EIPT	3-MAM
		DALT	Oripavine

Continues

Table 1
Continued

Aminoindanes	Benzodiazepines	Piperidines and pyrrolidines	Piperazines
MDAI	Flubromazolam	Ethylphenidate	Benzylpiperazine
Amphetamines	**Plants and extracts**	**Arylalkylamines**	**Others**
4-FMA	Ibogaine	MPA	G-130
5-EAPB	Mitragynine	2-MABB	PRE-084
Fenbutrazate	Mitragyna Speciosa	6-IT	2-MeO-difenidine
Phentermine	Tabernanthe Iboga	5-APB NBOMe	4,4-dimethylaminorex
Mazindol	Argyreia nervosa seeds	6-APB	Afloqualone
	Ipomoea violacea seeds	5-APB	MMQ
	Rivea corymbosa seeds	6-APDB	W-18
		5-APDB	Phendimetrazine
		5-IT	Nandrolone

on cannabis in Section B (substances and vegetable preparations, including extracts and dyes), nandrolone in Section A and tapentadol in Section D (previously included in Table II Section A) have been included respectively. Amfepramone and phentermine, have been excluded from Table II Section B. In Table IV, fonazepam (benzodiazepine analogue of flunitrazepam), methylmorphonate (methylphenidate anologue), sufentanil for sublingual use, etizolam and meprobamato have been included. In the Table of Medicinal Products, section D, lormetazepam has been included to the section "Compositions for use parenteral". In addition, the use of propilesedrine, except for the manufacture of barbesaclone, has been excluded. Moreover, the following substances have been excluded from the Table of Medicinal Products, Section B (dextropropoxyphene, fenproporex, mefenorex, meprobamate and tetrazepam), section C (dextropropoxyphene) and section E (meprobamate, dextropropoxyphene and tetrazepam). Conversely, cannabis-based herbal medicinal products have been included as usable in pain therapy in the Table of Medicinal Products, Section B. In Annex III-bis, tapentadol has been added to the list, previously included in Table II Section A. These decisions have been taken "to protect public health, in view of the risks associated with the use and spread of new psychoactive substances onto the international market", as the world of drugs is evolving every day, and has considerably changed in the last 10 years, with different forms of addiction, substances and modes of consumption.

CONCLUSION

The areas addressed offer an opportunity to recall that, in the Italian law, the penalty system for drug use and trafficking is based on Tables, and illicit conduct concerning (only) substances that are included in the "Tables" referred to in Articles 13 and 14 of Presidential Decree n. 309/90 are punished. The fact that the Ministry of Health, an administrative authority, has been entrusted with the task of drawing up and amending the "Tables" determines the construction of the criminal cases concerning narcotic or psychoactive substances as "blank criminal regulations", in which the sanction is determined by a legislative act, while the illegal conduct is only partly described, since it must be specified by the Ministerial Decree governing the individual substances. The adoption of the tabular system of substances subject to control determines that only conduct concerning substances included in the "Tables" may be sanctioned, both criminally and administratively. It is worth repeating the need for the complete and timely updating of these Tables, to avoid the effect of punishing conduct involving substances that, although dangerous, have not been tabulated. The problem arises in all its emergence for the so-called new psychoactive drugs (NPS) freely available on the Internet, although they produce stimulating and hallucinogenic effects similar to those of banned substances. They are obtained by modifying the chemical structures of the main illegal substances to obtain new substances that are not controlled and, for this reason, are called "legal highs". They are unregulated and untested. Given that the chemicals in these drugs are constantly changing to stay ahead of the law, it's possible to receive a very different product from batch to batch, even if the packaging and name are the same. The new molecules detected by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in 2018 are about sixty. Some of these have already been detected on Italian users, but as hundreds of other types are not yet listed in the "Tables" updated by the Ministry. Old and new generations of drugs are passing on the baton at a faster rate than bureaucratic procedures, and Italy is struggling.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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24. Italia. Decreto del Ministero della Salute, 21 dicembre 2007. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope e relative composizioni medicinali, di cui al decreto del Presidente della Repubblica del 9 ottobre 1990, n. 309 e successive modificazioni ed integrazioni, recante il testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope e di prevenzione, cura e riabilitazione dei relativi stati di tossicodipendenza: ricollocazione di talune composizioni medicinali a base di ossicodone in associazione con principi attivi non stupefacenti nella tabella II, sezione D. Gazzetta Ufficiale – Serie Generale n. 24, 29 gennaio 2008.
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33. Italia. Decreto del Ministero della Salute, 11 giugno 2010. Aggiornamento e completamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope relative a composizioni medicinali, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n, 309, e successive modificazioni ed integrazioni con l'inserimento dello steroide anabolizzante nandrolone. Gazzetta Ufficiale – Serie Generale n. 145, 24 giugno 2010.
34. Italia. Decreto del Ministero della Salute, 16 giugno 2010. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope relative a composizioni medicinali, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni ed integrazioni con l'inserimento delle sostanze denominate JWH-018, JWH-073 e Mefedrone. Gazzetta Ufficiale – Serie Generale n. 146, 25 giugno 2010.
35. Italia. Decreto del Ministero della Salute, 31 marzo 2011. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope relative a composizioni medicinali, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni ed integrazioni con l'inserimento del tapentadolo nell'allegato III-bis, e dei composti medicinali a base di tapentadolo, limitatamente alle forme farmaceutiche diverse da quella parenterale, nella tabella II, sezione D. Gazzetta Ufficiale – Serie Generale n. 88, 16 aprile 2011.
36. Italia. Decreto del Ministero della Salute, 11 maggio 2011. Aggiornamento e completamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e

psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni ed integrazioni. Inserimento nella tabella I delle sostanze 3,4-Metilendiossipirovalerone (MDPV), JWH-250, JWH-122 ed analoghi di struttura derivanti dal 3-fenilacetilindolo e dal 3-(1-naftoil)indolo. Gazzetta Ufficiale – Serie Generale n. 112, 16 maggio 2011.

37. Italia. Decreto del Ministero della Salute, 2 agosto 2011. Aggiornamento e completamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni ed integrazioni. Ricollocazione in tabella I delle sostanze Amfepramone (dietilpropione), Fendimetrazina, Fentermina e Mazindolo. Gazzetta Ufficiale – Serie Generale n. 180, 4 agosto 2011.
38. Italia. Decreto del Ministero della Salute, 29 dicembre 2011. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni ed integrazioni. Inserimento nella tabella I della sostanza Butilone o bk-MBDB, di taluni analoghi di struttura derivanti dal 2-amino-1-fenil-1-propanone e della sostanza AM-694 e analoghi di struttura derivanti dal 3-benzoilindolo. Gazzetta Ufficiale – Serie Generale n. 3, 4 gennaio 2012.
39. Italia. Decreto del Ministero della Salute, 11 giugno 2012. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella Tabella I delle sostanze 6-monoacetilmorfina o 6-MAM e 3-monoacetilmorfina o 3-MAM e sostituzione della denominazione chimica degli analoghi di struttura della sostanza Butilone. Gazzetta Ufficiale – Serie Generale n. 142, 20 giugno 2012.
40. Italia. Decreto del Ministero della Salute, 24 ottobre 2012. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope. Inserimento nella Tabella I delle sostanze: Metossietamina, 4-Metilamfetamina, CP 47,497, CP 47.497-omologo C8, 4-Fluoroamfetamina e 5,6-Metilendiossi-2-aminoindano. Gazzetta Ufficiale – Serie Generale n. 264, 12 novembre 2012.
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43. Italia. Decreto del Ministero della Salute, 23 gennaio 2013. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella Tabella II, Sezione B, dei medicinali di origine vegetale a base di cannabis (sostanze e preparazioni vegetali, inclusi estratti e tinture). Gazzetta Ufficiale – Serie Generale n. 33, 8 febbraio 2013.
44. Italia. Decreto del Ministero della Salute, 25 giugno 2013. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella Tabella I delle sostanze 6- (2-aminopropil) benzofurano (6-APB); 5-(2-aminopropil)benzofurano (5-APB); 6-(2-aminopropil)-2,3-diidrobenzofurano (6-APDB) e 5-(2-aminopropil)-2,3-diidrobenzofurano (5-APDB). Gazzetta Ufficiale – Serie Generale n. 158, 8 luglio 2013.
45. Italia. Decreto del Ministero della Salute, 8 gennaio 2015. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella Tabella IV delle sostanze etizolam e meprobamato e nella Tabella dei medicinali, Sezione D, dei medicinali ad uso parenterale a base di lormetazepam. Gazzetta Ufficiale – Serie Generale n. 22, 28 gennaio 2015.
46. Italia. Decreto del Ministero della Salute, 10 febbraio 2015. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni. Inserimento nella tabella I delle sostanze 4-iodo-2,5-dimetossi-N-(-2-metossibenzil) fenetilammina (25I-NBOMe) e 3,4-dicloro-N-(1-(dimetilammino)cicloesil)metil] benzamide (AH-7921), 1-cicloesil-4-(1,2-difeniletil)-piperazina (MT-45). Gazzetta Ufficiale – Serie Generale n. 48, 27 febbraio 2015.
47. Italia. Decreto del Ministero della Salute, 4 febbraio 2016. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Gazzetta Ufficiale – Serie Generale n. 41, 19 febbraio 2016.
48. Italia. Decreto del Ministero della Salute, 10 febbraio 2016. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella Tabella I delle sostanze HHMA, HMA e HMMA. Gazzetta Ufficiale – Serie Generale n. 51, 2 marzo 2016.
49. Italia. Decreto del Ministero della Salute, 1 agosto 2016. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre, n.309 e successive modificazioni e integrazioni. Inserimenti e ricollocazione di sostanze stupefacenti o psicotrope nelle tabelle I e IV, nella tabella dei medicinali sezioni A-B-D e nell'allegato III bis. Gazzetta Ufficiale – Serie Generale n. 187, 11 agosto 2016.
50. Italia. Decreto del Ministero della Salute, 13 marzo 2017. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella tabella I delle sostanze DOC e Acriloilfentanil. Gazzetta Ufficiale – Serie Generale n. 70, 24 marzo 2017.
51. Italia. Decreto del Ministero della Salute, 18 maggio 2018. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella tabella I e nella tabella IV di nuove sos-

tanze psicoattive. Gazzetta Ufficiale – Serie Generale n. 126, 1 giugno 2018.
52. Italia. Decreto del Ministero della Salute, 18 maggio 2018. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella Tabella I delle sostanze: XLR-11, 2C-E, 25H-NBOMe, 2C-H, 25E-NBOMe, 4-FMA, 6-EAPB, 5-EAPB, furanilfentanil. Gazzetta Ufficiale – Serie Generale n. 126, 1 giugno 2018.
53. Italia. Decreto del Ministero della Salute, 25 giugno 2018. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella tabella I delle sostanze Bufedrone, Pentedrone e Alfa-PVT. Gazzetta Ufficiale – Serie Generale n. 160, 12 luglio 2018.
54. Italia. Decreto del Ministero della Salute, 25 giugno 2018. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella tabella I delle sostanze Butirfentanil, 4-MEC, Etilone, MPA, 5F-APINACA. Gazzetta Ufficiale – Serie Generale n. 160, 12 luglio 2018.
55. Italia. Decreto del Ministero della Salute, 25 giugno 2018. Aggiornamento dell'elenco dei medicinali di cui all'Allegato III-bis del decreto del Presidente della Repubblica 9 ottobre 1990, n. 309. Gazzetta Ufficiale – Serie Generale n. 160, 12 luglio 2018.
56. Italia. Decreto del Ministero della Salute, 12 ottobre 2018. Aggiornamento delle tabelle contenenti l'indicazione delle sostanze stupefacenti e psicotrope, di cui al decreto del Presidente della Repubblica 9 ottobre 1990, n. 309 e successive modificazioni e integrazioni. Inserimento nella Tabella I delle sostanze: 3-Fenilpropanoilfentanil, 4-Fluoroisobutirfentanil (4F-iBF), Benzodiossolfentanil, Benzilfentanil, Benzoilfentanil, Carfentanil, Ciclopentilfentanil, Ciclopropilfentanil, Metossiacetilfentanil, Tetraidrofuranilfentanil (THF-F), Tetrametilciclopropanfentanil e Tiofenefentanil. Gazzetta Ufficiale – Serie Generale n. 255, 2 novembre 2018.