Clinical and Pharmacological, Forensic and Pharmaceutical Profile of Hallucinogenic Sage Salvia Divinorum: Regulatory Restrictions, Internet Accessibility to Consumers, Risks to Public Health in Italy

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Abstract. Salvia divinorum and Salvinorin A are an example of herbal psychoactive substances that combine high toxicological risk, rapid psychotropic action, and complexity of legal control. Their specific pharmacological profile, availability through online and informal markets, and perception as "natural" products create additional challenges for public health, forensic practice, and regulatory authorities. The extremely rapid onset of psychoactive effects, the potential for unpredictable behavioral reactions, and the difficulty of detecting use through routine toxicological screening further increase the relevance of these substances for medico-pharmaceutical law and forensic pharmacy. Italy's experience and the new EUDA mandate confirm that effective counteraction to such substances must be based on a combination of legislative control, forensic pharmaceuticals, monitoring of digital markets, prevention, early-warning mechanisms, public education, and preparedness of the health system. Particular attention should be paid to cross-border distribution, internet-based promotion, and the misleading marketing of psychoactive plants as harmless herbal products. Such an integrated approach is essential to reduce misuse, improve detection, support timely risk assessment, and strengthen cooperation between healthcare professionals, law-enforcement bodies, forensic experts, and regulatory institutions.

Keywords: Salvia divinorum, Salvinorin A, hallucinogenic legal high, Italian drug regulation, forensic pharmacy, novel psychoactive substances.

Introduction. The protection of life and health, as well as the rights and freedoms of every citizen and refugees from Ukraine living in a democratic society in Italy and other European Union Member States, is fundamentally guaranteed by the Constitution of Italy, particularly Articles 2, 3, 13, 16, and 32, and by the Charter of Fundamental Rights of the European Union, especially Articles 34 and 35 [1-4].

The life and health of minors, youth, and other age groups of citizens is affected by the availability of psychoactive substances prohibited for circulation Illegal trafficking of psychoactive substances is a global problem that threatens the life, health, and safety of citizens of the European Union member states, Italy, and Ukraine [5-11].

Studies show that the current situation with the drug business is complex, and psychoactive substances prohibited for circulation are produced, synthesized, processed, and sold on an unprecedented scale. That is why the European Union Agency for Drugs (EUDA) has been established, whose task is to anticipate (helping EU Member States to anticipate future drug-related challenges and their consequences); alerting (issuing real-time alerts about new drug-related risks and health and safety threats); response (assistance in strengthening their response to the drug phenomenon); training (facilitating knowledge sharing and training across the EU for evidence-based drug policy and interventions) [12].

The dynamics of increasing the level of illicit trafficking of illicit psychoactive substances in 2025 is confirmed by SCORE data [13]. 19 countries participated in the 2025 monitoring campaign (Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Finland, Hungary, Italy, Lithuania, Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden, Turkey). More than 75% of cities show higher loads of the cocaine metabolite benzoylecgonine (BE) in wastewater during the weekend (Friday to Monday) than on weekdays. About 50% of cities show a pattern in ketamine use, which has increased by almost 41%, the highest was recorded in cities in Belgium, Germany, and the Netherlands. Amphetamine detection was at significantly lower levels in cities in southern Europe, although more recent data suggest some indications of an increase in cities in Belgium, Denmark,

Norway, the Netherlands, Germany, Sweden. The use of methamphetamine was recorded at a low level in most cities in the Czech Republic and Slovakia, and was also noticeable in the wastewater of Spain, Cyprus, Lithuania, the Netherlands, Germany, Norway, and Turkey.

In recent years, the treatment of addictive disorders due to the abuse of new psychoactive substances in the world, in Italy, has faced a series of new challenges. This led to changes in the strategies of medical practice and clinical and pharmaceutical research [14-21]. Among the most pressing problems is the constant stigma associated with addiction, understanding addiction as a chronic disease. Social perception often continues to see it as a moral fault or personal weakness. Such stigmatization can discourage patients from seeking help and undermine recovery efforts. The emergence of new forms of addiction (gambling addiction, Internet and social media addiction, sex addiction and gaming disorder) are becoming more common, especially among minors and young people. The drastic distribution and online availability of new psychoactive substances pose difficulties for doctors, as new substances often go beyond approved clinical treatment protocols. Growing interest in the therapeutic use of certain psychoactive substances (for example, cannabis for the treatment of multiple sclerosis or psychedelic substances for the treatment of mental disorders). An increase in the number of comorbid disorders associated with the use of psychoactive substances (depression, anxiety, schizophrenia, and others). Effective treatment and pharmacotherapy of these comorbid diseases requires an interdisciplinary approach on the part of doctors. Addiction prevention also remains an underfunded and untapped aspect of addiction treatment in Italy. This requires the expansion of medical services, strengthening of preventive measures in medical services and programs of work with the community; strengthening control over the abuse of substances prohibited for circulation; increasing investment in prevention programs (educational intervention in schools, peer training, life skills training, harm reduction programs).

Among the psychoactive substances that have spread and become available via the Internet to young people in recent years is hallucinogenic sage – Salvia divinorum. It contains the psychoactive hallucinogen Salvinorin A.

The purpose of the study was to research the clinical and pharmacological, forensic and pharmaceutical profile of Salvia divinorum and Salvinorin A from the perspective of regulatory restrictions, Internet accessibility, risks to public health in Italy.

Materials and methods. In the process of preparing the article, bibliographic, analytical, regulatory, comparative, forensic pharmaceutical, content analysis and systematic research methods were used, which made it possible to comprehensively characterize the regulatory policy on combating illicit trafficking of Salvia divinorum, Salvinorin A in Italy, EU member states, the USA and Ukraine. materials from Italian, American, European, and other services.

The study of the article is a fragment of research works of Private Scientific Institution "Scientific and Research University of Medical Pharmaceutical Law" on the topic "Multidisciplinary research of post-traumatic stress disorders during war among patients (primarily combatants)" (state registration number 0124U002540, implementation period 2024-2029); Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" and Scientific Research Establishment of Innovations for Future LLC USA on the topic “Multimodal research on innovative legal, medical and pharmaceutical, clinical and pharmacological, behavioral-cognitive, psychological, socio-economic, medical and technological, forensic and pharmaceutical, and digital strategies for patient-centered pharmacotherapy of PTSD and associated diseases in war and conflict settings” (state registration number 0125U003297, implementation period 2025-2029).

Results and discussion. In the Member States of the European Union, there is a tendency to increase the level of illicit trafficking in narcotic drugs and new psychoactive substances [22]. There is a transformation of the illicit market for illicit psSychoactive substances. New psychoactive products are appearing, aimed at a wide range of consumers. There is an increase in violence related to the market of illicit drugs and psychoactive substances, that is, this is a significant difference, because 10 years ago, when we talked about drug-related violence and Central America, and now it happens almost everywhere in the member states of the European Union.

The European Union Agency for Drugs (EUDA) performs the functions of [23], Fig. 1.

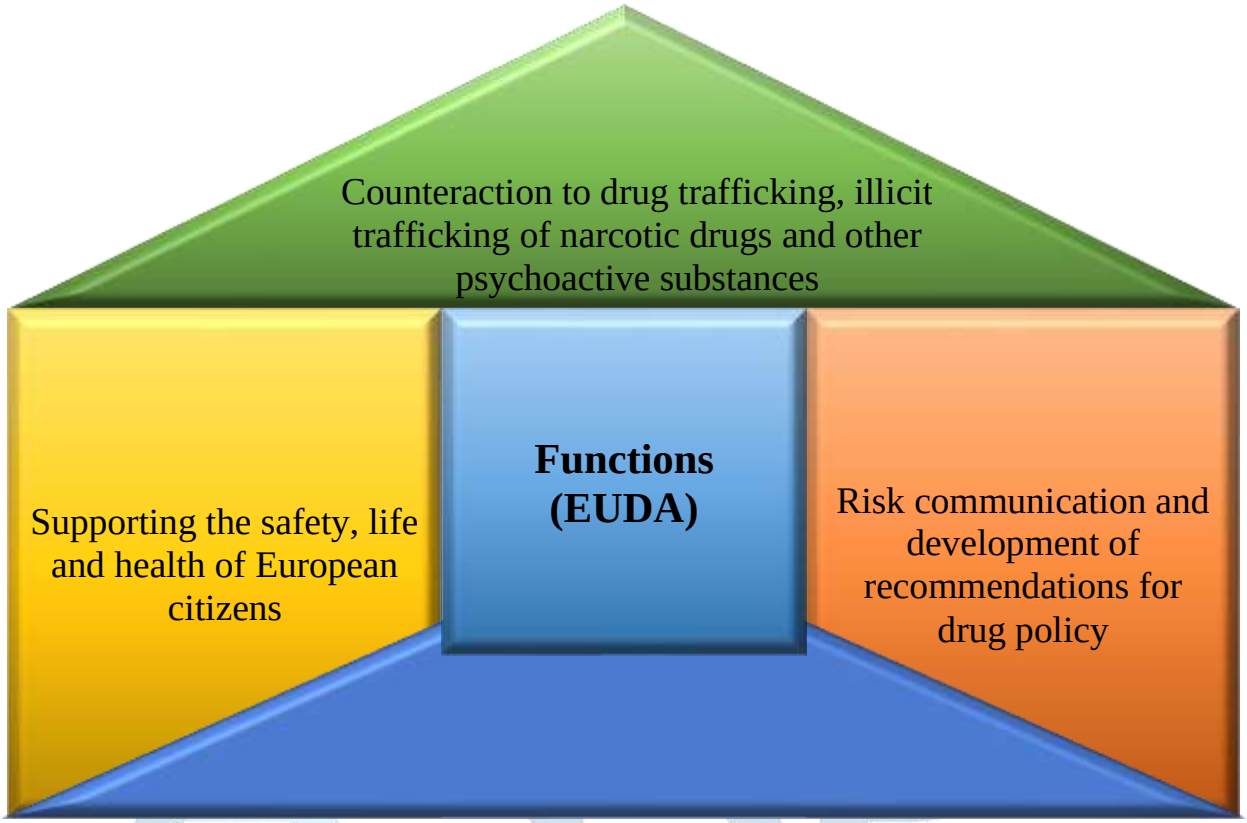


Fig. 1. Functions of the European Union Agency for Drugs (EUDA) [23].

In 2021, the expenditure of citizens in Italy on the abuse of illicit psychoactive substances reached approximately 15.5 billion euros [24-26], Fig. 2.

Prevalence and market of drugs

- 8.5% of the population abused cannabis products
- the average price of marijuana and hashish is 10.2–11.8 euros/g
- cannabis turnover on the black market - €6.6 billion
- the price of cocaine is 83.5 euros/g



Government spending

almost €1.2 billion for the treatment, prevention and rehabilitation of people with addiction



Mortality

227 deaths in 2023
Mostly people over the age of 40

84.14% of the deaths were males



Main causes of mortality

- heroin
- unknown psychoactive substances
- cocaine



Fig. 2. Abuse of illegal psychoactive substances in Italy [24-26].

New psychoactive substances are classified as "legal highs". They cause neuropsychiatric disorders, exacerbate comorbid disorders (addiction, tuberculosis, circulatory systems, vision, poisoning, suicide). Therefore, they are challenges for health care systems [27-35]. Availability via the Internet, online stores, "smart shops" contribute to the spread of salvinorin. Consumer misconceptions about the safety of sage are based on the absence of the plant and its products in the UN international lists for the control of narcotic drugs, psychotropic substances, and precursors. The leader of abuse is Salvia divinorum, a perennial plant native to Mexico (Fig. 3). Salvia divinorum gained notoriety for its intense, short-term hallucinogenic effects when smoking or chewing the leaves. The active ingredient is salvinorin A, a κ-opioid receptor agonist. It differs in mechanism from classical serotonergic hallucinogens such as LSD or psilocybin, but causes dissociative states, distortions, and potential psychomotor impairment [36-44].

The public health approach recognizes addiction as a complex medical and social problem. Salvia divinorum in Italy is classified as a psychoactive substance with hallucinogenic properties. It can cause dependence, mental pathologies, acute and depressive psychoses [45-47].

Clinical and pharmacological profile of Salvia divinorum, Salvinorin A

The active psychoactive ingredient of Salvia divinorum is Salvinorin A. Salvinorin A is a potent agonist of kappa opioid receptors. It does not contain nitrogen, which makes it unique among natural hallucinogens. It causes intense but short-term hallucinations, loss of movement control, uncontrollable laughter, and dissociation of mind and body. When inhaled, the effect occurs almost instantly (after 30 seconds) and lasts 5-20 minutes. The use of Salvinorin A for the treatment of chronic pain, depression, anxiety disorders and addictions is being investigated, however, human clinical trials are currently limited [48-53].

The chemical formula of Salvinorin A is shown in Fig. 4 [47].

Salvinorin A, a diterpene ester isolated from the leaves of Salvia divinorum (0.1-0.4% dry weight), is the main psychoactive component responsible for the hallucinogenic effects of the plant. Bioavailable sublingually, by smoking. It belongs to the Lamiaceae family.



Fig. 3. Hallucinogenic Salvia divinorum [36, 37].

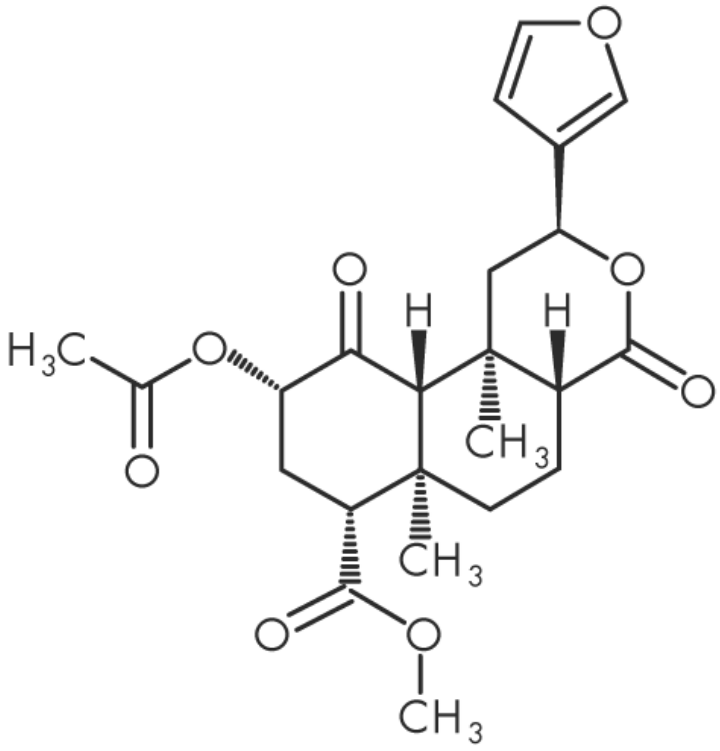


Fig. 4. The chemical formula of Salvinorin A [47].

Salvia divinorum Epling and Játiva-M., known as soothsayers' sage or hallucinogenic sage [36, 39, 40, 42, 43, 47]. It thrives in cloud forests at altitudes of 300-800 m above sea level, preferring shaded moist areas with rich moist soil along the banks of streams and ravines. The Salvia divinorum plant reaches 1.5-3 meters in height, with square stems, large oval leaves (up to 25 cm long) and inflorescences of white flowers emerging from purple-purple calyxes. The propagation of Salvia divinorum occurs vegetatively through cuttings that take root easily in water or moist soil, contributing to its spread beyond its natural range.

In its natural range, Salvia divinorum is closely related to the ethnopharmacology of the Mazatec people, who call it ska Pastora ("leaf of the Shepherd") or ska María Pastora ("leaf of Mary the Shepherd"), associated with the Virgin Mary. Mazatec shamans traditionally consume fresh leaves (chewing or as quid) during nocturnal rituals for divination (kauyum), spiritual healing, and treatment of ailments such as rheumatism, headaches, or gastrointestinal disorders. These ceremonies, documented since the 1930s, include an invocation to saints and require a quiet sacred place; The effects are described as visionary dialogues with the spirit of the plant, in stark contrast to modern recreational smoking practices. Ethnopharmacological studies emphasize its role along with other Mazatec hallucinogens such as morning glory (Rivea corymbosa) and psilocybin mushrooms, emphasizing its cultural significance as a non-addictive entheogen [36, 40, 42].

Outside of Mexico, Salvia divinorum does not occur naturally and is cultivated as an ornamental or psychoactive plant in temperate and tropical regions of the world, including greenhouses in the north. In Italy, despite the inclusion of controlled substances in Table I since 2006 (prohibiting cultivation, storage, and sale), clandestine cultivation indoors continues, often from imported cuttings under controlled conditions with high humidity (70-90%), temperatures of 15-25°C and rich, well-drained soil with perlite. Botanical gardens or research institutions may keep specimens under a permit for scientific purposes, but wild growth is absent due to an unsuitable Mediterranean climate without permanent cloud cover and humidity. Historically, online sellers sent live plants or cuttings to Italy before the measures were tightened.

The pharmacokinetics of Salvinorin A are characterized by rapid onset (peak effects 1-2 minutes after inhalation) and short duration (5-20 minutes), rapid pulmonary absorption, and high lipophilicity. Unlike opioids, Salvinorin A does not cause respiratory depression or euphoria, but provokes dissociative states: "unreality", loss of the body, vivid hallucinations (animation of objects, time dilation).

Clinically, Salvinorin A intoxications are manifested by acute mental symptoms: visual, auditory hallucinations (80-90% of cases), depersonalization, derealization (70%), motor incoordination (60%), anxiety, panic (50%). Data from monitoring centers (e.g., the United States) note tachycardia, dizziness, confusion, and agitation, but no lethality or organ toxicity [54].

Forensic and pharmaceutical risks. Patterns of use, Internet availability, «legal high» market

Recreational use of Salvia divinorum and Salvinorin A involves smoking dried leaves, concentrated extracts, with 3-5 deep puffs delayed for 20-30 seconds to maximize absorption. This method gives a peak of hallucinogenic (narcotic) effects in 30-60 seconds, lasting 5-15 minutes (up to 30-60 minutes). Traditional Mazatec oral quid (fresh leaves are chewed for 30 minutes) are rare in the Western context (<5%) due to the slow onset (10-20 minutes) and mild effects. Polydrug addiction is common (50-70% of cases), often with cannabis, alcohol, or stimulants to prolong the effects.

The legal high market thrives on the attractiveness of Salvia divinorum as a novel psychoactive substance. The products are disguised as incense, potpourri or "herbal relaxants" ("Lady Salvia", "Fortune Leaf"). Until 2006, Italy was widely sold on the Internet from the EU (Netherlands, UK) in ordinary envelopes, bypassing customs. After regulation, the Internet supports deliveries with "research chems" or seeds. Global e-commerce (AvalonMagicPlants) restricts Italy but uses a proxy. Seizures in Italy (2020-2025) – 500+ kg/year. Despite legal restrictions in many countries, Salvia divinorum seeds and leaves are often offered through foreign online shops and "smart shops" as a "legal buzz". Products are often marketed as concentrated extracts; the actual concentration of Salvinorin A may be unknown and dangerously high. Consequences of uncontrolled use of Salvia

divinorum and Salvinorin A for the health of consumers: can provoke long-term psychosis in vulnerable individuals; loss of coordination and orientation creates a high risk of injury; Products purchased online do not have quality certificates, which leads to unpredictable and often overly intense reactions [35, 51, 53, 55, 56].

In the controlled environment of Italy (Table I since 2006), patterns are shifting to underground networks: head shops have been renamed "smartshops" with legal analogues, social networks (Instagram, TikTok) with instructions for home cultivation. EMCDDA notes the growth of spice mixes.

Pharmacists need to be vigilant when handling herbal relaxants. OTC departments risk criminal violations, which requires education on pharmaceutical law, on the risks of illegal trafficking of Salvinorin A, reports of suspicious import shipments of goods containing Salvinorin A to AIFA, Carabinieri NAS.

Legal status of Salvia divinorum, Salvinorin A

In the Italian criminal law, Salvinorin A is included in Table I. Clinical, pharmacological, toxicological, and forensic pharmaceutical data inform consumers about side effects and risks of use. The patient often requires maintenance therapy (benzodiazepines) during treatment. Long-term risks (e.g. provocation of psychosis) are like those of ketamine. In modern conditions, the relationship between the USA, Mexico, Italy, Ukraine, and other EU member states is supported constant communication. Citizens of all ages, young people travel and study in colleges. Therefore, there are criminal and forensic pharmaceutical risks regarding the spread of the level of illegal trafficking of Salvia divinorum, Salvinorin A. Monitoring records cases of intense psychological distress, loss of coordination among young people. Salvia divinorum and Salvinorin A have become subject to controls in Belgium, Denmark, Italy, Latvia, Lithuania, Romania, Sweden, Australia, Japan, in a number of US states. Croatia, Germany, Poland, and Spain regulate only this plant Salvia divinorum. In Estonia, Finland and Norway, Salvia divinorum is subject to drug legislation. Finally, in Canada, the sale of Salvia divinorum without a permit is illegal under the Natural Health Products Regulation [45, 46].

In Italy, Salvinorin A., and the plant Salvia divinorum were included in Schedule I (Table I) of prohibited psychotropic substances in March 2005. The cultivation of Salvia divinorum or possession of more than 0.5 mg of Salvinorin A is punishable by imprisonment for a term of 6 to 20 years. Salvia divinorum is sold on the Internet in the form of extracts with instructions for use, without describing side effects, harm to human health due to abuse [57].

The legal status of Salvia divinorum in the United States varies, with control over the circulation of psychoactive substances carried out by the Drug Enforcement Administration (DEA) and the FDA [54, 55, 58]. At the federal level, the DEA has indicated that Salvia divinorum and its psychoactive hallucinogen Salvinorin A are not controlled by the Controlled Substances Act. 29 U.S. states have passed laws prohibiting trafficking Salvia divinorum and Salvinorin A. The use of Salvia divinorum is most common among young people aged 18-25 years; individuals who have had experience with risky behaviors (sale of illicit substances, theft) or the use of prohibited hallucinogens, ecstasy. The results of the 2006 National Survey on Drug Use and Health (NSDUH) showed that about 1.8 million minors from the age of 12 used Salvia divinorum during their life, and approximately 750,000 used Salvia divinorum during the 2009 Monitoring the Future survey showed that 5.7% of 12th grade students reported using Salvia divinorum. Individuals 18-25 years old were more likely to consume Salvia divinorum compared to 12-17-year-olds. Men were more likely than women to consume Salvia divinorum. Salvia divinorum use among college students was more common among white men, who frequently smoked marijuana and showed low levels of self-control. Significant prevalence of co-use of nicotine with other psychoactive substances (alcohol, marijuana, narcotics, hallucinogens).

In Ukraine, Salvia divinorum, Salvinorin A is included in the "List No. 2 of Table I" of the list of narcotic drugs, psychotropic substances and precursors by the Resolution of the Cabinet of Ministers of Ukraine dated 31.05.2010 No. 373 [59].

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Subsequently, by the Resolution of the Cabinet of Ministers of Ukraine dated 23.05.2012 No. 408 Salvia divinorum is excluded from the list of prohibited narcotic drugs, psychotropic substances, and precursors [60]. However, this does not mean that Salvia divinorum has become legal in Ukraine. In paragraph 3 of the same resolution, in note 2, it is stated that the same control measures are carried out for plants or parts thereof containing any product included in List No. 1 of Table IV, as in relation to the specified remedy.

The Ministry of Health of Italy is a public administration body that coordinates the national system of health, veterinary medicine, and food safety in Italy. The experience of the US DEA and the US FDA in controlling the circulation of Salvia divinorum requires study by the State Service of Ukraine on Medicines and Drug Control and the State Expert Center of the Ministry of Health of Ukraine, as an authorized state institution that provides preclinical study, clinical trials, and state registration of medicines, as well as pharmacological surveillance (safety monitoring) in Ukraine.

In Italy, the circulation (distribution, abuse) of Salvia divinorum provoked decisive action on the part of the Ministry of Health and law enforcement agencies. Accepted:

- Decree of the Italian Ministry of Health of December 22, 2006 (subsequent updates) from 2004-2006 both Salvia divinorum and Salvinorin A are included in Table I of controlled substances under national anti-narcotic laws (equating them to highly dangerous narcotic drugs with criminal sanctions for illicit trafficking (storage, transportation, marketing, sale, cultivation;
- Systemic changes that reflect Italy's active position in the EU, where several member states (e.g. Belgium, Denmark, Sweden) have introduced similar controls on illegal trafficking, despite the absence of Salvia divinorum in UN conventions. The criminal legal acts adopted in Italy contribute to the fight against illicit trafficking with a simultaneous emphasis on the protection of public health, when illicit trafficking, even in small quantities (approximately 0.5 mg of Salvinorin A), capable of giving psychoactive doses (hallucinogenic effect), constitute a crime, and the Italian citizen who committed this crime is criminally liable.

In Italy, trafficking, illegal possession of prohibited psychoactive substances is regulated by Presidential Decree No. 309/1990 (Consolidated Law on Drugs) [45-47, 57-62].

- ✓ Article 73 of the Consolidated Law defines the following actions as punishable:

• cultivation, production, manufacture, extraction, processing;
• agreement, offer, sale, transfer, receipt, acquisition for others, distribution, trade;
• carrying, despatching, transiting, transiting in transit, shipping, and possession;
• export and import of drugs.

Among all types of offenses related to the possession and trafficking of drugs, it is necessary to distinguish separately:

- ✓ Article 74 – regulates the crime of a criminal community for the purpose of illegal trafficking of drugs or psychotropic substances;
- ✓ Article 79 – promoting the use of narcotic substances;
- ✓ Article 82 – incitement of others to use narcotics, proselytism, and inclination to use.

The legal approach in Italy to the circulation of Salvia divinorum and Salvinorin A is set out in the Decreto Ministeriale (DM) of December 22, 2006. Salvinorin A is included in Table I of substances with "hallucinogenic properties capable of causing states of abuse and manifesting latent mental pathologies (acute and depressive psychoses, possibly irreversible)" according to Presidential Decree (DPR) 309/1990 (Testo Unico sulle Droghe). This classification equates Salvinorin A with Schedule I drugs such as heroin or LSD. Storage, cultivation, production, and trade are prohibited. Low personal use (up to 250 mg of dry leaves or equivalent) entails administrative measures (prevention, therapy); Trafficking – 6-20 years in prison and fines of up to €26,000. Subsequent updates (DM 2016, 2020) extended controls to plant material and derivatives, closing loopholes for extracts as "incense".

After 2004, control of new hallucinogens was introduced based on reports of abuse of young people. Application – Carabinieri NAS (anti-counterfeiting), Customs and AIFA, with seizures of 200-500 kg/year (2018-2025).

Conclusions. Salvia divinorum and Salvinorin A demonstrate the challenges posed by herbal "legal highs", which often escape international control but require strict national measures due to pronounced dissociative and hallucinogenic effects. The review confirmed the clinical and pharmacological profile of Salvia divinorum and Salvinorin A (psychiatric disorders). Internet accessibility remains one of the key channels for the distribution of Salvia divinorum and Salvinorin A, highlighting the limits of purely prohibitive approaches and the need for enhanced cross-border controls. The experience of Italy, where Salvia divinorum and salvinorin A were included in Table I according to DM on January 11, 2005 and subsequently brought to the plane of strict control, demonstrates a proactive model of combining legal restrictions with forensic pharmaceutical supervision. Public health strategies should prioritize preventive education, emergency preparedness, and ongoing NPS monitoring, rather than being limited to reactive prohibitions.

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Data availability statement. The datasets analyzed during the current study are available from the corresponding author on reasonable request.

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