The Recent Legal Approach to New Psycho-Active Substances Regulation in Israel: Does it Work?

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Abstract

Background: New Psychoactive Substances (NPS), rapidly spreading on the global drug market have become a major concern in different Countries. The drug control systems did not allow a prompt and effective response to this phenomenon, due to the slow and complicated procedures to declare a substance dangerous and illegal.

Aims: To briefly summarize to legal background of drug control in Israel and illustrate the characteristics of the novel legislation.

Method: The Authors summarize the legal approach to NPS control in Europe and in New Zealand, the first Country to opt for a pre-market approval regime for NPS, describing the legal alternative sad opted and describe the Israeli Law for the Fight against the Phenomenon of the Use of Dangerous Substances.

Findings: The new legislation succeeded to close kiosks and retailers, marketing NPS to youth and young adults in the Country. The law is unique in that it includes both an urgent temporary declaration, whose violation is penal, banning a substance as dangerous with its inclusion after 12 months into the First Schedule of the Dangerous Drugs Ordinance, and the empowerment of the police forces to search, seize and destroy the dangerous substance, constituting an administrative procedure. The law is enforced using a novel, integrated model of enforcement, providing the cooperation of different control agencies, and avoiding to criminalize the consumers.

Conclusions: The effectiveness of this legislation, although promising short-term results have been registered, has still to be ascertained and more time is needed in order to perform a scientific evaluation of its results but meanwhile its impact is already noticed in the Court decisions, which make a difference between NPS and other drugs such as Cannabis in the severity of the penalties.

Keywords: Israel; NPS; Dangerous substances; Synthetic cannabinoids; Urgent declaration; The law for the fight against the phenomenon of the use of dangerous substances

Introduction

During the last few years the rapid emergence of a myriad of new psychoactive substances (NPS), openly marketed as "legal highs" had a strong influence on the pattern of drug use in different Countries, especially affecting the young population due to their easy accessibility and relatively low price [1]. Some of these substances derived from products synthesized by the pharmaceutical research which did not receive the marketing license, due to some dangerous property. Others have been illicitly synthesized. They are generally sold as herbs or incense products, mainly consisting of Damiana leaves sprayed with toxic substances and synthetic cannabinoid mixtures. In Israel they were initially freely sold in shops and kiosks, with exciting names such as "Hertzel gives you wings", 'Mabsuton' and others, in colorful packages. Since 2009 over 80 illicitly produced synthetic cannabinoids have been identified and notified through the Early Warning System to the EMCCDA (European Monitoring Center for Drug and Drug Addiction) and its members in order to improve their tracking and control [2]. Many more substances are constantly produced and marketed via websites, including the dark-net, or sold in kiosks or head shops. The fast and regular appearance of new psychoactive compounds renders their inclusion and specific listing practically impossible and overwhelms the chance to perform substance -by-substance risk assessments. Moreover the lack of sufficient human toxicological data and the insufficient case report of intoxications or deaths under their use by Emergency Services hinder the possibility to give evidence that synthetic cannabinoids are hazardous to the public [2]. As a reaction to the enactment of legislations attempting at the outright ban of scheduled substances, we witnessed the fast release to the market of new synthetic substances, with minimal chemical changes, claiming not to contain any new unscheduled substances [3], thus making the effort of controlling them straining to the traditional drug regulation system, characterized by slow procedures and the need of basic scientific data on their harm potential [4,5]. Many Countries implemented policies of massive media-reports of dramatic case stories concerning specific substances, such as in Israel "Mr. Nice Guy", creating a "moral panic" atmosphere, resulting in the increased awareness of the banned substance and consequently the use of new yet-to-be-scheduled drugs with unknown harmful properties [5]. Due to the complexity of this scenario special caution needs to be used when deciding upon the preferable legal regulation in order to avoid unwanted negative consequences. In this paper we intend to present the situation in Israel concerning the regulation on NPS and the legislations issued in order

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to control their marketing and distribution, in an effort to reduce their harm to the population, after a brief review of the different legislations enacted in some other Countries. We will also discuss the effectiveness of the new legislation to further improve the control on these new synthetic psycho-active substances.

**NPS and Health Risks**

The main concern with the use of these synthetic substances is their still unknown health hazard, both immediate and long-term, after acute or chronic use. In the majority of the cases there is a lack of comprehensive scientific data concerning their toxicology; addiction potential and long-term consequences on physical and mental health. Interestingly relatively safe, tobacco-free herbal smoking mixtures have been available for many years. By 2006 it became clear that certain herbal products under the brand name of ‘Spice’ mimicked the effects of THC, without containing it. Only in 2008 the first illicit synthetic cannabinoids were identified in these smoking mixtures [2]. Another important issue is that under the same brand name, such as “Hagigat”, different substances are identified from one time to the other, for example at the beginning meth-cathinone and in time methamphetamine were introduced together with other toxic substances, making very hard for both the consumers and the regulators to address the issue of their potential effects and harm. Most of the users are minors or young adults, frequently misbelieving that these compounds are legal and harmless and, being a very sensitive population, this renders the issue even more complicated [6]. Another major problem is the lack of reliable urine or blood tests for the detection of these substances, a fact which has a great impact on the capability of the Emergency Units staff to detect the substance in case of intoxication or severe medical condition and deciding for the right intervention, thus endangering the patient. In Israel the most popular NPS is “Mr. Nice Guy”, lately used not only for recreational purpose by the young, but also by opioid-addicted patients in Methadone maintenance treatment as a street-drug. The use of these substances by this chronic population introduced the practice of injecting them with; as a consequence, the recent increase of newly infected HIV cases. Few death cases were also reported in the last year in Israel mainly due to the use of these substances by injection, in combination with alcohol or other drugs. The most frequent adverse effects reported include sharp increase in blood pressure, cardiac problems, tremor, epileptic fits, acute anxiety and paranoid reactions. Due to the difficulty to detect them in urine tests they are used by additional populations, such as soldiers during their compulsory military service, people in treatment centers or jail, users under mandatory drug screening for ex. on the basis of suspended sentences. Some regular consumers of cannabis opt for cannabinoids due to their legal status, easy availability and lower price, being unaware that some cannabinoids, such as JWH-210 or JWH- are respectively 90 and 35 times more potent than THC [7]. The experience in Israel showed that probably due to their potency these substances may cause severe mental reactions mainly acute psychoses, characterized by the appearance of micro-zootic hallucinatory states, aggressive behavior, and delirium like states, leading to long psychiatric hospitalizations, due to the lack of prompt response of these patients to anti-psychotics. Some cases also developed schizophrenia even after sporadic use.

**Legal Control on NPS in Europe**

Facing the rapid and aggressive marketing of NPS, characterized by a fast turn-over of substances, the EU had to find new models of legal control, seeking accelerated ways to declare these substances as dangerous and curtail their open and legal sale [8]. On the base of insufficient evidence the main dilemma was a disproportionate response versus no response. Drug control has been addressed mainly as a criminal justice problem although the United Nations Office on Drugs and Crime (UNODOC) already acknowledged in 2009 that this approach had not been efficient in protecting public health and promoted broader responses beyond the punitive principle [9]. Many Countries opted for alternative control systems facilitating rapid responses in order to control the drug market without penalizing possessors for consumption. One driven by the “precautionary principle” for consumer safety, with proportionality between measures taken and level of protection to the public [10]. The rapid responses device has to be accompanied by a risk assessment procedure of the substance, including the consideration of the recent scientific knowledge on the product. A critical problem that has also been aroused is the definition of “low risk” level that is not always well defined in the different legislations, creating the possibility to side-step the enforcement of the law. There are countries, such as Poland, where the costs of the risk assessment procedure is at the expenses of the manufacturer and not of the taxpayer, a well recommended step. The goal of rapid control measures is to avoid unregulated potentially harmful substances to be released on the market for long periods of time with subsequent associated harms, such as it happened for BZP(Benzyl-piperazine) recreational pills in New Zealand [11]. Another great problem undermining the effective implementation of these legal control tools is the cost of enforcement in a period of limited financial resources in many Countries, a fact which creates great disparity among the Countries. In order to reduce the high costs of enforcement the use of import bans on dangerous substances, such as methedrone in the UK, could also contribute to the removal of the substance from the market, especially in those Countries where the custom drug control policy is efficient [12]. It was mainly the occurrence of fatal incidents and the pressure of the public opinion that influenced the Countries to advocate stricter legal control measures on NPS, for ex. the closure of “smart shops” in Poland after some 200 adolescents were hospitalized due to adverse effects of ‘Spice’, or the enactment of stricter legislations on NPS in Romania and Bulgaria after the public concern for the increase in NPS use [1,9]. EMCDDA(European Monitoring Center on Drugs and Drug Addiction) reported as for 2012 the shortcomings of the existing legislations to control the marketing and distribution of NPS in Europe mainly due to the long and reactive evaluation procedures and favored fast and effective legal instruments to control NPS including temporary bans [13]. The systems used by different States to prohibit or curb the use and marketing of drugs including NPS belong to three different models: 1.The List Model- which lists individual drugs, chemically defined in legislations or Ministerial Decrees; 2.The Analogue System Model- which includes drugs based on the similarity of their chemical structure. In this approach a substance is banned if it is structurally similar and its “chemical” effect is similar to another controlled and illicit drug. This simple approach, widely criticized, is enforced in the US; 3.The Generic Legislation Model- which prohibits clusters of substances showing similarity with an existing illicit drug. This kind of model is an attempt to introduce “future proof” legislation, banning all existing drugs and possible analogues still to appear in the drug market in the future without performing individual drug risk assessment [14]. Many European Countries introduced generic or generic-like legislations, claiming that this model of legislation is in accordance with the “precautionary principle” so that fewer people will be exposed to the potential risks of putative harmful NPS. Nevertheless several disadvantages in the implementation of this kind of legislation model have been mentioned, such as the inclusion of useful substances, hindering the development of potential new medicines, the increase of
the administrative burden on industry, government and economy including an increase in the application for exemptions. In addition the identification of growing number of NPS challenges the laboratories, needing high analytical standards and reference materials to compare, with high costs [11]. Moreover the introduction of a generic law might violate the principle of legality, without clearly stated penalty provision and lack of accountability to the citizens. Some European Countries have therefore chosen the application of alternatives to generic legislation. Among the alternatives Denmark, Spain, Germany, UK and the Netherlands introduced emergency ban procedures by Ministerial Decree. For ex. in the UK “The Temporary Class Order” empowers the government to temporarily ban a drug for a period of 12 months, during which a risk assessment to evaluate the dangerousness of the substance will be performed. The UK government also addressed the trading of these substances by enforcing the “Consumer Protection for Unfair Trading Regulations”, 2008. If for ex. an NPS is marketed as a “bath salt” or “fertilizer” it violates the law and its distributor can be legally prosecuted [12]. NPS can be also effectively controlled by means of legislations regulating products safety, including nutrients for the consumers, with proper labeling requirements. For ex. in Italy “Spice” was seized because it was not properly labeled in Italian [13]. In 2009 Austria blocked the import and sales of “Spice” without criminalizing the users through the implementation of the European Medicine Directive 2001/83/EC ensuring that medicinal products are delivered in the Member States only with proper authorization [1]. Also sales or age restrictions may be feasible, similar to the restriction of alcohol or tobacco sales to minors and the burden of proof may be shifted to the retailer. Violation of these laws can result in fines, revocation of the sales license or closure of the outlets [5]. An interesting new legislation model has been adopted recently by New Zealand, establishing the world’s first pre-market approval regulatory regime for NPS, similar to regimes applied for medicines. This new regulatory framework was established in 2013 with the enactment of the Psychoactive Substances Act (PSA) [14] which provides that NPS which can be shown with pre-clinical and clinical scientific trials data to pose “no more than a low risk of harm” will be approved for legal manufacture, marketing and sale. The producers interested to introduce these NPS to the market are also required to sponsor the product risk assessment and to pay an application fee. Other restrictions imposed are the minimum purchase age of 18 and no sales at convenience stores. The advertising is also limited to the point of sale and should include only information on the product and its price. Moreover there is a requirement that the product includes a list of all ingredients, health warnings and contact details of the National Poisons Centre [15,16]. The rationale for the introduction of this “out of the box” legislation is that once a regulated market for NPS is established the majority of the NPS purchase will be made from the legal market. However it may be that unapproved and illegal NPS will be much cheaper, due to the high costs of the risk assessment, more powerful, because they are not supposed to pose low risk, thus attracting more consumers. On the other hand approved NPS have the advantage of being legal and giving some guarantee of safety and quality, being strictly supervised. Being the legislation rather recent its effectiveness is still to be proved and a post-approval monitoring, similar to pharmacovigilance, is required but many challenges exist, for example the combination of approved NPS with alcohol or other drugs, different ways of administration such as injecting, long-term adverse effects, high consumption episodes and the notification of only rare severe reactions. The incentives to the producers have to be clear, with gain outweighing costs, particularly considering that most of the manufacturers of NPS produce other illicit substances and, being profit-driven, it is unlikely that they will opt for a legal market if the expected demand will not be large enough but on the base of estimations on the sale data of NPS in New Zealand it is suggested that the global market could be substantial [17]. More time is requested in order to conclude whether this courageous initiative from the New Zealand government will prove effective to control the NPS illegal market or it will remain a symbolic act [18].

The European Commission in 2013 proposed a new regulation, based partly on the idea that a legitimate market for NPS requires adequate protection and suggested that “low risk” NPS should not acted upon at the EU level while “moderate risks” substances should be prohibited and “high risks” substances should be submitted to drug control measures, but in this proposal the cost of the assessment will not be at the expenses of the producer and this arose certain concern among the member states [19]. Three European Countries(Ireland, Poland and Romania), as New Zealand have chosen to reverse the established control model and two of them, Poland and Romania even introduced “pre-market approval regime”. All three Countries seem up to now to have some success in stopping the NPS illegal market [20]. The NPS rapid expansion in the world has given the opportunity to think about alternative legal approaches and policies, that seem to be equally effective in protecting public health as the traditional ones, being much more efficient and fast but conclusive data need objective and rigorous long-term evaluation [5].

Legal Background on Drugs Control in Israel

Any psycho-active substance with evidence-based dangerousness to the public, including physical or mental harm and the potential for addiction is banned to the public and is claimed illegal upon its inclusion and scheduling into the Dangerous Drugs Ordinance, [New Version], 1973 [21,22]. A ‘Dangerous Drug’ is defined by law as “a substance listed in the First Schedule, including any of its salts, as well as any preparation, compound, mixture or solution made from the aforementioned substance and its salts.” The procedure required to ban a substance is a long bureaucratic process, which after the emergence of the NPS on the drug scene, did not succeed to give a prompt and adequate response to control the new market characteristics and prevent harm to the public. The procedure requires different steps:

1. The chemical and toxicological analysis of the substance and its attribution to a family of compounds, according to its characteristics, and its similarity to other illicit substances, by the Laboratory of Criminal Identification of the Ministry of Defense.

2. The risk assessment of the substance, concerning its potential harm to the physical or mental health of people using it on the base of the existing world literature and the report of death or intoxication cases from the medical services and the compilation of an extensive expertise by the Enforcement and Inspection Division of the Ministry of Health.

3. The recommendation by a multi-ministerial, multi-disciplinary expert committee – the Psychoactive Substances Committee at the Israel Anti-Drug Authority – including professional experts from different disciplines such as chemists, pharmacologists, narcologists, specialists in addiction medicine, police officers, other law enforcement agents and representatives of the relevant Ministries(Ministry of Defense, Justice, Health).

4. Upon recommendation of the Psychoactive Substances Committee of the inclusion of a determined psycho-active substance into the Dangerous Drugs Ordinance the Minister of Health is entitled, according to article 41 of the Ordinance, to
decide for its inclusion by compiling and signing a special form.

5. This decision is discussed and finally approved by the Committee for Labor, Welfare and Health at the Knesset (Israeli Parliament) and the list of the newly included substances is then published in the legal Reshumot (the official document where laws are published) and the Ordinance is then updated and amended.

Due to this complicated process, it takes months in order to ban a substance and therefore no prompt response to the intensive marketing of various designer drugs became possible, a fact which prompted the relevant authorities to opt for a different and shorter regulatory process in the case of the NPS. Due to the problem that the illicit manufacturers of designer drugs rapidly released new substances by a simple change in the original molecule, thus circumventing the law, and the slow process could not stop the phenomenon, in 2010 it was decided to amend the Ordinance (Amendment of the First Schedule) by including for the first time families of substances. The Amendment, commonly known as “the Derivatives Law”, was enacted starting from the month of August 2010, and implied the inclusion of four families of designer drugs-Cathinones, Metcathinones, Amphetamines, Methamphetamines, “including their isomers and their derivatives”.

Later on an additional family of drugs was included, the 2-Amino- indanes. The law defines a structural derivative as “a substance in which there is a transformation (by replacement, addiction, subtraction or substitution) of one or more chemical groups on/from its chemical structure.”

This amendment constituted a remarkably efficacious legal tool to improve the enforcement upon synthetic designer drugs being sold mainly in kiosks and shops and the prevention of the marketing of these dangerous substances particularly to the adolescents and young adults, unaware of the inclusion of different toxic compounds in the apparently “innocent” herbal highs packages. It is important to notice that upon its enactment, the Amendment succeeded to cover up to 80% of the possible combinations of the designer drugs [23,24].

After the release of different synthetic cannabinoids in the market, such as JWH-018, HU-210, JWH-073, causing serious harm to the young users, especially acute psychosis frequently requiring their compulsory hospitalization, a second Amendment of the Dangerous Drugs Ordinance (Amendment of the First Schedule) was issued in 2013 [25] as an attempt to contain the spreading of these substances and their harmful consequences to the public. This second “Derivatives Law” was issued on May 6, 2013 and was published in the Reshumot on May 9, 2013 (where official records and laws are published) and could be implemented immediately. This second Amendment was an extension of the previous one and it included the banning of synthetic cannabinoids and their derivatives.

Moreover, in order to avoid any misunderstanding among the illicit producers and vendors, certain substances, marketed on a large scale, were introduced in the Ordinance specifically, one by one.

The Law for the Fight against the Phenomenon of the Use of Dangerous Substances

Albeit the enactment of the second Declaration, the drug scenario in Israel continued to be characterized by the illicit selling of synthetic cannabinoids and other designer drugs, both in kiosks and on the websites, thus creating growing panic among the parents population concerning the possible harm to their children. The illicit drugs producers challenged the drug control system including the police enforcement attempts. Under these circumstances the Minister of Interior Defense, Aharonowitz promoted to join forces in order to fight this uncontrollable phenomenon and summoned an inter-ministerial Board whose aim was to propose a series of solutions both in the enforcement and in the legal fields. In the enforcement domain it was proposed to build an integrated and multi-structured model, practicing the authority power of all relevant bodies: the Israeli Police Forces, the Ministry of Health, the Local Government, the Tax Authority, the Authority for the Protection of the Consumer, the Legal Attorney. In the legal field it was promoted the advancement of new legislations, allowing the utilization of multiple tools in the service of a better enforcement. As the result of the cooperation of the different relevant Ministries, the Law for the Fight against the Phenomenon of the use of Dangerous Drugs was passed in 2013 [26]. Among the fundaments of this law it should be mentioned the increased power and authority conferred to the Police forces in order to improve seizures and rapid destruction of the dangerous substances upon the right to a hearing given to the producers or sellers, reversing the burden of proof to them. Another important issue of the law is the solution found for the interim period till the inclusion of the dangerous substances in the Drug Ordinance, giving the entitlement to the Minister of Health, to issue an Urgent Declaration of a substance as prohibited to be distributed during a period of twelve months, on the base of a reasonable assumption that it will be included in the Dangerous Drugs Ordinance. Article 1 of the law defines a “dangerous substance” as “a substance intended for human use by way of eating, drinking, chewing, injecting, infusing, smoking or sniffing and in respect of which a reasonable assumption exists that its use is likely to lead to a breach of the public order or the public peace, endanger the public security or health, similarly to the harm caused as the result of the use of a dangerous drug” [26]. The law prohibits the import, production, selling, and distribution of any substance declared as dangerous. Article 2 of the law states that a substance should be deemed dangerous either if it doesn’t comply with the requirements for the labeling of a product, (for example evidence of all its ingredients is not clearly stated), according to the Public Health Ordinance (Food)-[New Version], 5743, 1983 [27], the Pharmacists Ordinance [New Version] 5741-1981 [28] or the Consumer Protection Law, 5741-1981 [29], either if it causes similar effects to the user as those caused by the use of a dangerous drug. In order to improve the enforcement concerning dangerous substances the law empowers the police officers to perform search and seizure of the substance [section 2- article 3] and in case they actually seize the dangerous substance they are supposed to summon the possessor to appear in front of a police officer, at the rank of Inspector or above it, within 7 days, for a hearing, before a decision is taken to actually destroy the substance. After the decision to destroy the substance is taken, the destruction will take place after a period of 30 days and it will be carried out by a police officer especially appointed to do so. The possessor has the right to appeal to the Court in a civil proceeding within 30 days of the decision. The Court may order the cancellation of the decision to destroy the substance if it came to the conclusion, after examining the circumstances, the type of substance, the place where it was seized, the possessor identity, that the substance is not dangerous [section 2, article 4].

Together with this new legislation, for the first time in Israel, it was instituted a multi-agency enforcement model, coordinated by the Police forces, responsible for the respect of the public order. They are empowered to do so according to the article 338 of the Penal Law, 1977 [30]. The Ministry of Health, namely the Enforcement and Inspection Division, is empowered to do so according to the Pharmacists Ordinance
indanes, and since then this practice is regularly implemented and it achieved some promising results in the curbing of the market of these substances by intensive enforcement [23-25], but it was not until 2013, with the enactment of the Law for the Fight against the Phenomenon of the Use of Dangerous Substances [32] that a real breakthrough was observed. This legislation is the first in Israel to provide a temporary and immediate ban of every substance deemed to be dangerous for a period of 12 months and meanwhile the regular process for the inclusion of the substance into the First Schedule of the Dangerous Drugs Ordinance is performed. This legislation focuses on the distributors and not on the consumers, non-penalizing the users. By the help of other relevant legislations, such as the Pharmacist Ordinance [New version], 1981 or the Business Licensing Law, 1968 [31] a multi-agency enforcement model is activated, thus achieving a more active control of the retail point-of-sale and closing the outlet if proved to act illegally. The new law has shown to be very practical and fast, allowing better coordination between the different regulation agencies in the Country. Since its enactment the massive and wide-spread sale of the NPS in kiosks has been successfully stopped. Recently the sale is more on the websites or through blogs and the sellers provide a take-home service. The Israeli Police in cooperation with other enforcement Bureaus, such as the Ministry of Health Enforcement and Inspection Division and the Israeli Anti-Drug Authority is nowadays considering developing a cyber-drug control system, in order to reduce even more the accessibility of these substances to the public, although there exists general consensus that complete prohibition or limitation of Internet sales is counter-productive and is not a feasible option, taking in consideration the fact that the market will always find new ways to deliver the drug [1]. Recently the Israeli Court came to a good knowledge of this law and dangerousness of this phenomenon, namely the wide-spread marketing of NPS and their serious health consequences, and in many Court decisions, including confinement till the end of the proceedings, they make a difference between drugs such as cannabis and the new psychoactive substances, deciding for more severe penalties in case of they make a difference between drugs such as cannabis and the new psychoactive substances, deciding for more severe penalties in case of

Discussion

Current drug laws failed to control the marketing and sale of new psychoactive substances principally because of the slow and complicated procedures linked with their inclusion in the Drug Control Laws and the need for a novel and an urgent solution emerged all over the world. In Europe three levels of control, based on NPS analogy to drugs controlled by International Conventions exist since 1997: an early warning system (EWS), risk assessment by the EMCDDA scientific committee on potential dangerous drugs and European political decisions advocating new legislations [18]. In Israel the first step was to opt for a generic-like amendment of the First Schedule of the Dangerous Drugs Ordinance, the “Derivatives Law” which was consequently updated with the inclusion of cannabinoids and 2 amino-


20. EMCCDA (European Monitoring Centre for Drugs and Drug Addiction) (2014) Legal approaches to controlling new psychoactive substances.


25. Amendment of Dangerous Drugs Ordinance (Amendment of the First Schedule) 2013, State of Israel.


27. Public Health Ordinance (Food)-[New Version], 1983, State of Israel.


