Legal highs – legal aspects and legislative solutions

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Abstract

In recent years the attention of society, the media and politicians has focused on the negative phenomenon of the occurrence of an enormous amount of new psychoactive substances flooding the European market. In Poland and in Europe they are known under the name 'legal highs' or 'smart drugs'. In many countries these compounds present a serious social and health problem. The core of the problem is the fact that in the light of the law these substances are legal, while actually they imitate the effect of illegal narcotics. Smart drugs are sold allegedly as 'products not intended for human consumption', under the cover of 'collector's commodities', 'incense sticks' or 'bath salts'. Efforts undertaken by many countries, including Poland, are biased towards gaining control over this pathological phenomenon by placing the subsequent substances on the list of prohibited agents. However, the resilient chemical and pharmaceutical industry still remains one step ahead by introducing new derivatives of already banned products, practically identical in action. The presented article is an attempt to bring closer the problem of smart drugs in Poland, from the occurrence of this alarming phenomenon, through the spread of sales in shops all over Poland, to a series of changes in the Polish anti-narcotic law, drastic actions of closing the shops throughout the entire country, and transferring the sale of smart drugs to the internet.

Key words

legal highs, smarts, designer drugs, boosters, legal regulations, new risk, public health

INTRODUCTION

In the last few years, the phenomenon of new psychoactive and intoxicating substances has undergone many dynamic changes. An enormous number of new synthetic substances flooded the European markets, in many countries beyond legal control [1]. This mainly concerns new psychoactive substances which are legal, but possess the activity of many illegal narcotics. In the European countries and worldwide they are known under the names: 'legal highs', 'smarts' or 'herbal highs', while in Poland they became known as socalled 'boosters' [2, 3]. The term 'boosters' covers a wide spectrum of products, from synthetic or designer drugs to herbal mixtures. These products are usually advertised in various ways, as incense sticks, room fresheners, or even bath salts. Resiliently, these products are designed, for example, as 'animal food' or 'plant fertilizer'; they are also sold as 'collector's commodities' or 'coloured bags'. The packages bear warning labels: 'definitely not intended for human consumption' [4]. Frequently, boosters are mixtures of fragments of plants (herbs) with extracts of other plants, as well as synthetic, chemical substances [5]. The majority of these products had not been tested, neither on animals nor on humans, prior to introduction to the market [4].

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These substances were divided into three categories: stimulants, depressants and hallucinogens. They are available in various forms, e.g. pills, roll-ups, herb mixtures, powders and salts. They may contain natural plants (e.g. *Kratom, Kava kava, Saliva divinorum*), synthetic substances (e.g. 2-aminoindan, butylone, mephedrone) and semi-synthetic substances originating from natural oils (e.g. DMAA) [2]. A group of chemical compounds which are a basic component of herb mixtures should also be mentioned, e.g. JWH-018 or JWH-122 – substitutes of THC acting in a way similar to marihuana [6].

'Boosters' are often sold in sealed packages bearing various hippy and 'new age' symbols. Many products are labeled with inscriptions or passwords which remind consumers of the slang names for narcotics and the effects they induce, e.g. 'Snow Blow', 'White Ice Resin', 'Sub-Coca', 'X Pillz', 'Chaos', 'Diablo', 'Snow Power', 'Moon Dust', 'Golden Bullet', 'Lucifer', 'Happy Pink', 'Trans', 'Summer Daze', 'Dragon Blister', 'TaiFun', 'Groove' or 'Dynamind Euphoria' [2, 3]. Sales are carried out by retail shops, so-called 'smart shops', 'head shops', and also 'fun shops', located in many European cities. Very frequently, the producers offer their products via the Internet.

Legal highs' market. In recent years, a dramatic increase has been observed in the sale of legal highs via the Internet [5]. Until 2008 in Poland, psychoactive substances appeared to a small degree on websites through mail-order shops. Initially, this phenomenon was limited; however, within more than one year it developed to a considerable extent [7].

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Studies on the availability of boosters on the market describe hundreds of various products which contain a variety of psychoactive substances at different doses, forms (powder or salts) and additives [2]. These are specially designed substances, aimed at effective exclusion from legal control by the State. The pace and way in which the market responds to the means of control, as well as such phenomena as globalization and innovatisation of producers, are an increasingly greater challenge for the present approach to new psychoactive substances [1]. The availability of some products may quickly change according to the creation of new substances (analogues) in response to legal control by the State [2]. In most cases, the producers of 'boosters', after banning certain products, introduce into turnover new versions of these substances slightly changed in chemical formulae, and also with a new, attractive name. Due to this, the chasing and legal control of these substances is a big problem for law enforcement authorities [4]. This is reflected not only by an increasing number, but also various types of compounds which appeared on the Polish and European markets.

The idea of introducing new substances to replace those subjected to legal control is not new. In the past, these substances were illegally produced and sold directly on the illegal market (e.g. derivatives of phentanyl and ring substituted phenylethylamine in the 1980s, tryptamines in the 1990, and piperazine and cathinone derivatives at the beginning of 2000). Nowadays, the drug producers innovative approach is based on obtaining the chemical substances needed for drug production from legal sources, and then selling what is in fact a drug substitute - as an allegedly legal product. [1]. In recent years, the main groups of most frequently used chemical compounds have been derivatives of piperazine and phentolamine, tryptamine and cathinone. At present, some derivatives of these substances are under legal control. For example, in 2008, 13 European Union (EU) member states banned benzopiperazine (BZP) and other piperazine derivatives. In response, the producers slightly modified the chemical formula of the substance and began producing a new BZP-free pill [2, 8].

The size of the current market of legal highs in Europe is difficult to estimate. Nevertheless, the scale of the phenomenon may be presented by the example of the United Kingdom, where it is estimated that during the period 2002-2006, over 2 million pills with BZP - so-called 'party pills' - were sold. Local media estimate the home market of legal highs at the value of 2 million pounds; however, the precision of these estimates is questioned [8]. At the beginning of 2008, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) reported 68 websites selling legal highs in the entire territory of the EU. More than a half of them (52%) had their seat in the United Kingdom, 37% in Holland, 6% in Germany, 4% in Austria, and only 1% of them were detected in such countries as Ireland and Poland [9].

Legal highs in Poland – brief history. In Poland, the source of today's phenomenon may be sought for at the beginning of the 1990s when the political changes caused an economic increase, openness to western markets, and there began a commodities exchange with the European countries which, unfortunately, resulted in an increase in the use of drugs. On the home drug market, such compounds as ecstasy (MDMA), amphetamine and heroin found a multitude of new fans. These compounds became increasingly cheaper and more available to a large portion of the young population. Law enforcement agencies observed the increased interest of organised crime in the production and trade of narcotics, which caused the transition of Poland into one of the top European countries producing large amounts of high quality amphetamine. This growing phenomenon had to result in intervention by the State; therefore, between 1999/2001 the first Polish National Programme for Drug Addiction Control was performed, aimed at limiting the demand and supply of drugs. This programme resulted in limiting the activity of criminal groups dealing with the production and sale of drugs, as well as the prophylaxis and treatment of addicts [6].

In 2008, the phenomenon of legal highs began to be observed in Poland. The website www.dopalacze.com, began its activity on a wide scale, which offered their clients legal collector's commodities' with psychoactive properties. All products were sold in very interesting wrappings, with an attractive and modern appearance. Due to the tremendous interest, the owners decided to open a standard retail shop. The opening took place after a large scale advertising campaign at the end of August 2008 in Łódź. Within the subsequent 6 months, over 40 such shops were opened throughout the country [10]. Prices per one dose were on the level of 40–60 PLN, but some of them reached over 100 PLN [11]. The presence of the shops evoked interest among young inhabitants interested in the purchase of legal highs. It also attracted the attention of public opinion and the authorities which, however, were helpless because of gaps in the law in effect. In the light of the Polish law, smart drugs were not narcotics, therefore their turnover and distribution were not associated with legal consequences. This phenomenon was relatively strongly exposed by the media which began discussions concerning the legality of these products, as well as their effect on the young population as the main consumers [7].

Legal highs – national legal regulations. Until 2008, the major legal act still in effect in Poland concerning anti-drug regulations remains the Act in the Matter of Drug Prevention of 29 July 2005 [12]. This Act specifies the following:

- principles and mode of procedure with respect to drugaddiction prevention;
- principles and authorities of State and local administration organs and other institutions concerning violation of the law pertaining to narcotics;
- 3) proper agencies for the execution of the Act;
- 4) penalties for non-observance of statutory provisions and regulations.

According to Clause 2 of the Act, counteracting drug addiction is performed by the proper shaping of social, economic, educational ad health policy, especially:

- 1) educational, informative and preventive activities;
- 2) treatment, rehabilitation and reintegration of those addicted;
- 3) reduction of health and social loss;
- 4) surveillance of substances, the use of which may lead to drug-addiction;
- 5) control of illegal turnover, production, processing, designing and possession of substances, the use of which may lead to drug addiction;
- 6) control of plant crops containing substances, the use of which may lead to drug-addiction [12].

Further on, the Act also regulates the competences of the National Bureau for Drug Prevention, and Drugs and Drug-Addiction Information Centre functioning within the structures of the National Bureau. The executive Act possessing the rank of regulation delineating the priorities of counteracting drug-addiction in Poland is the National Programme for Drug Control. The most important goal of this Programme is 'Reduction in drug use and associated with it social and health costs'. The performance of the Programme and, in fact, the principal goal, covers 5 domains: prophylaxis, treatment, rehabilitation, limitation of health loss and social reintegration, reduction of supply, international cooperation, research and monitoring. The National Programme for Drug Control is fully integrated with anti-drug strategy and the European Union plan of action [7]. Unfortunately, this Act - with all its provisions and regulations - did not cover control of new psychoactive substances, and in the light of regulations, these substances were not included on the list of substances prohibited by the Act. Therefore, the need arose to make substantial changes and eliminate the legal gap for the phenomenon of 'legal highs'.

In mid-2009, a working team presided over by the Chief Pharmaceutical Inspector, developed changes in the system, aimed at the minimization of the hazardous phenomenon of smart drugs [13]. According to the assumptions of the project, the new system would be based on a procedure consisting of several elementary stages:

1) active monitoring;

2) preliminary assessment;

3) temporary control;

 risk assessment, as well as evaluation of the consequences of legislation;

5) constant control or cessation of control.

The decision would be issued by 2 teams possessing the budget needed for performing the studies and analyses. The first team would consist of representatives from the central agencies who would be engaged in wielding control over the legal and pharmaceutical markets, aimed at the detection of suspicious products introduced to the market which create risk for health and life of consumers, the supervision of precursors turnover, as well as control of the underground narcotics business.

The second expert group would consist of scientists in various specialties, so-called technical support. The results of their efforts would be presented to the Minister of Health in the form of a report concerning the assessment of risk and evaluation of the results of the registration of a substance under State control. In turn, if needed, the Minister of Health would decide to start legislative procedure. In addition, there would exist 2 legal mechanisms, such as: temporary control of the substance and accelerated procedure of implementing control over the substance, in the case of compounds with respect to which there would be a suspicion of their being hazardous for consumers' health [7].

Changes of legal guidelines in the face of new risk for public health. At present, the standard procedure for the control of new substances introduced under the legal control in Poland starts with the preparation of a project by an agency subordinated to the Ministry of Health for the matters of drug addiction, i.e. National Bureau for Drug Prevention, according to Act 6, Clause 3 of the Act of 29 July 2005 [12]. The subsequent step is carrying out public consultations, after which the text is submitted to the Cabinet. After acceptance by the cabinet, the government bill is introduced into Parliament for acceptance. The First Chamber of Parliament (Sejm) votes after three readings, and then submits the bill to the Second Chamber – the Senate. When the Senate has made its decision, the text is passed to the President to be signed into law. The Act is subsequently published in the Official Journal and usually comes into force within 21 days. In urgent cases, this procedure may be initiated by the Cabinet upon application by the Minister of Health. An emergency also means a shorter time for issuing decisions by both Chambers of Parliament, as well as the President. The duration of the standard procedure is usually approximately 9 months, while the quick procedure – at least 3 months [14].

In response to the phenomenon of legal highs, the first amendment to the Act of Drug Control was introduced in 2009. The amendment expanded the list of substances under State control concerning BZP, JWH-10, and 15 plants (Argyreia nervosa, Banisteriopsis caapi, Calea zacatechichi, Catha edulis, Echinopsis pachanoi, Kava kava, Leonotis leonurum, Mimos tenuiflora, Mitragyna speciosa, Nymphea caerulea, Peganum harmala, Rivea corymbosa, Salvia divinorum, Tabernanthe iboga, Trichocereus peruvoanus) with psychoactive properties, where there was a suspicion that they occur as components of legal highs [15].

In 2010, a subsequent amendment was made to the Act, and the list of hazardous substances was expanded by mephedrone and 7 other synthetic cannabinoids (JWH-073, JWH-398, JWH-250, JWH-200, CP 47,497 and its homologues C6, C8, C9, HU-210) [16]. Unfortunately, these changes did not significantly result in a change of this pathological phenomenon. According to calculations by the Minister of Health, in the middle of 2010 there were over 1,000 shops with legal highs throughout Poland. In the second half of 2010, there occurred more signals concerning medical assistance and hospitalization of patients suspected of the use of legal highs. They complained of such alarming symptoms as: excitation, anxiety, slurred speech, tachycardia, high blood pressure (over 180), nausea, vomiting, sweats, abdominal pain, convulsions, hallucinations, sometimes leading to psychosis. After use, legal highs disturbed the function of the cardiovascular, nervous, digestive and endocrine systems [11]. At the end of September, the media reported at least several acute intoxications and two lethal cases after the use of legal highs. Unfortunately, there was no clear confirmation by toxicological laboratories whether death was caused by the consumption of legal highs [17]. The rapidly growing supply of these substances which, in practice, are legal substitutes for illegal drugs (over 1,000 retail outlets within the last two years), as well as further information concerning poisonings and deaths in association with the use of legal highs, caused a strong response by society in the form of many protests and informative campaigns on local and national levels. On 3 October 2010, several hundred national sanitary inspectors and about 3,000 policemen started action aimed at closing shops selling legal highs in Poland. According to the decision by the Chief Sanitary Inspector, all shops selling legal highs were closed [18]. The decision by Chief Sanitary Inspector to close shops selling legal highs, as well as warehouses and enterprises producing them, was based on Article 27, Clauses 1 and Clause 2, and based on the Article 31 of the Act of 14 March 1985 in the matter of the State Sanitary Inspectorate [19]. This decision states that:

- 1. The collector's product named 'Tajfun' is withdrawn from sales, together with other similar products which may cause a direct risk for human life and health;
- 2. Economic activity is prohibited, including the production, wholesale and retail sale to enterprises dealing with products hereby mentioned in Clause 1;
- 3. The decision is subject to instant execution [20].

At this time, the inspection was carried out of 1,100 retail outlets, warehouses and manufacturers. More than 900 of them were closed. Sanitary inspectors and police intervened in almost 1,000 selected retail outlets and warehouses [21]. Apart from this, activities aimed at the discontinuation of the sale of legal boosters in Poland, in order to eliminate the direct risk for public health, the government prepared in a casual way, a subsequent, third amendment to the Act in the Matter Drug Addiction Control, and the Act in the Matter of the National Sanitary Inspectorate. The Act, without additional amendments, was passed through both chambers of Parliament, was signed by the President, and entered into force on 27 November 2010 [22]. The amendment to the Act introduced several innovative instruments which, until now, have rarely been applied in Polish law. The amendment introduced the following changes in the Polish anti-drug law: in Article 4, Clause 27, it introduces a modification of the definition of a substitute agent, which is a substance of natural or synthetic origin in any physical state, or a product, plant, fungus, or their component, containing such a substance, used instead of an intoxicating agent or a psychotropic substance, the production of which and introduction into turnover is not regulated, based on separate regulations; with respect to substitute agents the regulations do not apply concerning the general safety of products. The definition refers to psychotropic substances and intoxicating products, which, according to the Act, mean all substances classified in this Act.

- 1. Article 20, Clause 3, introduces a ban on advertisements suggesting that an improper application of the product may cause psychoactive effects similar to those obtained after the consumption of psychotropic or intoxicating agents. The violation of the above-mentioned regulations is subject to a fine, penalty of restricted liberty, or penalty of deprivation of liberty for up to 3 years.
- 2. Article 44b of the Act prohibits the production and introduction into turnover of a substitute agent.

The institution responsible for the control is the Chief Sanitary Inspector. According to Article 52a of the Act, violation of the prohibition of introducing into turnover of a substitute agent is subject to a fine ranging from 20,000 PLN – 1,000 000 PLN. The fine is imposed by the decision of a proper sanitary inspector. While establishing the fine, sanitary inspector considers the scale of activity, i.e. the amount of a substitute agent which is introduced to sales. Apart from changes considered in the amendment to the Act in the Matter of Drug Control [23], amendments were also introduced to the Act in the Matter of the National Sanitary Inspectorate. The legislator decided to modify the legal regulations concerning the general safety of food products. Article 27b introduced states that in the case of justified suspicion that the product may be hazardous, the proper sanitary inspector may withdraw the product for the period of 18 months needed for its examination and testing for its hazardous effect. This regulation does not include products regulated by separate regulations. In addition, sanitary inspectors have the right to suspend the economic activity carried out for the period of 3 months in order to eliminate risk. Furthermore, Article 27b introduces solutions associated with the cost of carrying out the study and analysis procedure. These costs are borne by the subject of legal proceedings. However, if, in the course of examination and expertise, it is proved that the product does not create any risk for human life and health, these costs are reimbursed [22, 23].

Despite the support from public opinion and a considerable compromise concerning changes among politicians, the Act was criticized by some journalists and experts, mainly constitutionalists, human rights activists, and specialists in matters of drug addiction treatment [24, 25]. Some constitutionalists claim that the Act is not in accordance with the principle of the clarity of law, which is guaranteed in the Constitution of the Republic of Poland and in effect in the Polish legal system. Human rights activists admit that the incompatibility of this principle in practice will leave much space for fraud on the part of State institutions and public administration. Subsequently, the lack of adequate procedures is pinpointed and conditions which must be met by the sanitary inspector during the evaluation of risk associated with the product. [26] While the amendment to the Act in the Matter of Drug Control was being passed, Parliament considered other legislative initiatives associated with legal highs. One of the projects of amendment to the Act was submitted by the Social and Liberal Democrats (SLD) on the verge of 2008 - 2009. This project presented a more liberal approach to the problem of legal highs. The main assumption was approaching legal highs in the same way as alcohol and tobacco. The control of the State would cover the ban on selling to the under-aged, and specify what products may be sold by obtaining permission for production and sales. The prohibition of sales via the Internet and the ordering of placing a warning label concerning the hazardous effect of the product on the package and in the shop were proposed [27]. The subsequent project for the Act was submitted by the Law and Justice (PiS) party, according to which the status of legal highs was placed on the same level as pharmaceuticals, and the process similar to that applied to-date for the registration of new pharmaceutics would be required from the subjects introducing the substances into turnover. In addition, the project assumed the imposition of high penalty sanctions for violation of the regulations [28, 29]. Nevertheless, Parliament decided to pass the amendment proposed in the project submitted by the government.

At the beginning of 2011, in order to keep pace with innovations on the market of legal highs, a subsequent, fourth amendment to the Act was presented. The Act introduced additional psychoactive compounds to the prohibition list, including: synthetic canabinoids, which are the component of herbal mixtures (JWH-007; JWH-019; JWH-081; JWH-122; JWH-203; JWH-210; and also AM-694 i RCS-4), cathinone derivatives, natural alcaloids present in the African plant khat (*Catha edulis*) (4-EMC; 4-MEC; 4-FMC; methadrone; metamfepramone), metylone, butylone, piperazine derivatives (TFMPP; pFPP; MBZP), phenylethyloamine derivatives (2C-E; MDPEA; MDPV), fluoroamphetamine, and naphyrone. The Act came into force on 8 June 2011 [30-32].

Legal highs as a public health problem in the EU countries. At present, drug control policy is mainly under

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the competence of the member countries, while the European Commission is responsible for the monitoring and evaluation of the EU drug control strategy and plans of actions with respect to narcotics. Poland, as a member of the European Union, is obliged to perform EU projects in the area of drug addiction control, as well as fulfill decisions by the European Commission. Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk-assessment, and control of new psychoactive substances, established a new mechanism for swift exchange of information concerning new psychoactive substances which may create risk for public health and society, including risk on the part of organized crime [33]. This system was to enable the European Union institutions and EU member states to take efficient actions against new psychoactive substances and intoxicating agents occurring on the narcotic markets in Europe. This Decision also covers evaluation of risk associated with new substances. Such an evaluation of risk studies health and social hazards created by the consumption, production and sales of new psychoactive substances, as well as the participation of organized crime, and possible consequences of the application of the means of control. Essentially, the means applied in the member states in the area of drug control and psychoactive substances could also be used with respect to new psychoactive substances.

In compliance with the provisions of Article 4, the EMCDDA and Europol closely cooperate with the national focal points (NFP) REITOX (The European information network on drugs and drug addiction) and Europol National Units (ENUs) which jointly perform the primary role in the detection and reporting of new psychoactive substances. In addition, in compliance with the provisions of Article 5 of the Decision, EMCDDA and Europol, in association with the European Medicines Agency (EMA), are obliged to collect, analyze and present information concerning new psychoactive substances in the form of a joint report. The joint report contains evidence-based suggestions for the Council and Commission for the needs of conclusion about the evaluation of risk due to new psychoactive substances [1].

Unfortunately, the latest report by the European Commission shows that in 2010 a nearly two-fold increase was observed in the number of new psychoactive compounds. In 2009, 24 new substances appeared on the European market, whereas a year later as many as 41 new intoxicating drugs appeared [34]. Access to these compounds increases at an alarming pace or rate. At present in the EU, the introduction of substances to the prohibition list (a six-stage procedure) takes about a year, efforts are undertaken to accelerate this process, because it seems that the system in effect is not efficient enough and does not keep pace with the development of the designer drugs industry. In the autumn this year, proposals for new solutions and changes of procedures in the strategy of legal highs control should appear. It is proposed, among other things, to implement a more flexible system, similar to that in force in the matter of food safety, where enforcing a ban on an individual product lasts for a very short time and is performed in an emergency mode by all the member states [35].

CONCLUSIONS

Considering the rapid technological progress, cheap organic synthesis, accompanied by an increase in the use of the Internet and sales of new narcotics, it may be expected that synthetic analogues of various groups of narcotics will continue to appear. In this context of the phenomenon of legal highs, it may be expected that the concept of new narcotics will continue to evolve at an unprecedented pace. Law enacted by politicians still tries to catch up with the realities of life; unfortunately, this has little chance in the face of contemporary chemistry and pharmacy. Including subsequent compounds on the list of prohibited agents does not bring about the desired effects, because new substances continue to appear, slightly modified, under a new name and with very similar effect. The constant game of cat-andmouse by the State agencies and producers of legal highs may be endless, and unfortunately the criminals are always one step ahead [27]. It is important to consider the risk associated with the transition of legal highs onto the Internet market, initially propelled by individual levels of enterprise, and finally taken over by organized crime. Doubts which arose with respect to some methods which the government used in control of legal highs should be taken into account, as well as the essence of the amendments to the Act in the Matter of Drug Control. This is associated with the opinion of the Committee for European Integration which issued a negative opinion concerning new legal regulations. According to the CEI, amendments violate the right of the free movement of goods within the EU countries [36]. The thing is that more than a half of the plants included on the list of prohibited agents are legal in West European countries, and furthermore, are used in the pharmaceutical and cosmetic industries [37].

In addition, within recent weeks, it has appeared that the decision by the Chief Sanitary Inspector to close all shops selling legal highs, was unlawful. In the opinion of lawyers, the Chief Sanitary Inspectorate should not have issued one decision concerning the closing of all shops, but as many decisions concerning as many shops as it wanted to close. This creates legal grounds for high compensations which the owners of the shops afflicted by this decision may claim by taking legal actions [38]. There still remains an open question: which organs of the State should control the phenomenon of sales/consumption of legal highs hazardous from the aspect of public health, in order to act effectively, complex, and primarily in compliance with national and EU law?

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