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Possibilities of implementing harm reduction program for smokers. Current status and recommendations

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HIGHLIGHTS
Novel tobacco products enable harm reduction programs.

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ABSTRACT

On September 30th, 2019, the editorial debate of the quarterly "Neuropsychiatry. Clinical Review" took place in Warsaw, dedicated to the possibilities of implementing the harm reduction programs in nicotine addiction. The scientific organizer was the Polish Neuropsychiatric Association. The publication is the result of this meeting. The debate was to establish the status praesens, to review research analyses and understand controversies, as well as to outline the perspectives of practical implementation of harm reduction programs. In addition, the possibilities of legal changes and new medical standards were indicated.

Smoking is the most important, modifiable, cause of many diseases and premature mortality. Tobacco smokers become addicted not only to nicotine, but also to other substances included in cigarette smoke. Addiction is also influenced by cultural and social factors. A number of new tobacco products that do not work by smoking have a 90–95% reduction of toxic ingredients comparing to the composition of cigarette smoke. While lowering level of carcinogens is obviously beneficial, the long-term effects of these new products have not yet been established. The low effectiveness of the available methods of pharmacotherapy for nicotine addiction creates premises for the implementation of harm reduction programs using new products with modified risk. Such concepts are supported by state regulators in developed countries, creating special registration paths, taking into account the fact that the toxicity of new products is reduced. Precedent registrations of the products with reduced risk of harm (FDA, USA) create conditions to replace pragmatically smoking tobacco products – with other, less harmful ones.

Key words: modified risk tobacco products, heat-not-burn products, novel tobacco products, harm reduction programs

INTRODUCTION

Taking into account virtually every point of reference, health-related harm stemming from cigarette smoking is amongst the most severe ones [1]. 100 million people died as a result of tobacco smoking in the 20th century, and it is forecast that 1 billion will die of the same cause in the 21st century [1]. In order to take proper stock of the damage incurred, one should consider it not only from the medical perspective, but also in an economic, cultural and legal context [2]. The fundamental ambivalence, consisting in the fact that particular states draw economic benefits from cigarette manufacturing, while generating health losses at the same time, has not yet been reconciled or resolved. Presently, tobacco smoking is the second cause of death worldwide, following arterial hypertension, with passive smoking independently ranked thirteen [3].

In such a situation, any possible option of harm reduction appears to be worthy of consideration [4]. A landmark FDA registration in April 2019 of a heated tobacco product that "produces fewer or lower levels of some toxins than combustible cigarettes" [5], opens up such possibilities. FDA is currently reviewing an even further reaching registration of a "modified-risk tobacco product" [6], which would in fact constitute a harm reduction program in itself. Novel tobacco products, as indicated in the research conducted in collaboration with the public healthcare systems [7], make it possible not only to limit the risks involved, but may also contribute to a cessation of nicotine intake altogether, irrespective of its route of delivery.

EPIDEMIOLOGY OF SMOKING

In 2017, 24% of the 15+ population was found to smoke every day in Poland [8]. It was a survey-based finding, which took into account both cigarettes coming from legal and illegal sources. The percentage of smokers in Poland only started to drop in the 1990s, whereas elsewhere in the world that process had begun

back in the 1970s [9]. Despite the downwards trend, however, the decline is quite slow or even stagnant now in Poland [8]. On the other hand, taking into consideration the collection of excise duties on tobacco products, the number of legally purchased cigarettes has been on the rise since 2016, with the related state income totaling 19.8 million zlotys in 2018. That increase may be relativized, vis-a-vis the actual number of smokers, as a result of the ever shrinking grey market, reduced tobacco smuggling, and disappearance of illicit tobacco products, or as a result of the influx of economic migrants from Eastern Europe, but the rise in sales volume remains a fact [10].

There are five anti-nicotine clinics in Poland [9]. Occasionally, the National Health Fund (NFZ) launches additional anti-nicotine programs. Altogether, we spend ca. 1 million Polish zlotys on counseling of the type. The modest budget can hardly produce a significant population-wide effect. The available anti-nicotine drugs are not reimbursed. Thus, practically speaking, we do not have a system of anti-nicotine treatment in place. Additionally, VAT and excise tax on tobacco sale constitute a significant source of income for the Polish state: proceeds from excise duties on tobacco products account for one third of the entire revenue from excise tax [10]. Following the fuel industry, the tobacco industry ranks second as a donor of public funds, delivering 8% of the total annual revenue budget, and creating over 500 thousand jobs in agriculture, processing, manufacturing, and trade [10]. Those criticizing the status quo indicate, however, that economic benefits do not compensate for the direct and indirect costs of tobacco smoking [4]. The greatest prevalence of smoking is reported for Indonesia (39.9%), Russia (30.3%), Greece (27.3%) and Turkey (26.3%) [11]. It is worth mentioning that there are more smokers in Poland than in Germany (18.8%), in the UK (17.2%) or the US (10.5%) [11]. We may assume that as compared with the situation in the 1970s, lifestyle-related tobacco smoking has been reduced, and those who continue to smoke are either people who were already addicted back then or have a psychobiological susceptibility to nicotine. The percentage of smokers across the world has gradually been declining, but the scale of medical sequelae has remained the same, as the world population is growing in absolute terms.

CIGARETTES, E-CIGARETTES AND TOBACCO HEATING DEVICES

Nicotine is primarily delivered to the body via inhalation, which requires the generation of aerosol, produced by heating. It is also possible to deliver nicotine directly via the mucosa of the oral cavity (snus) or the nose (snuff). From the medical standpoint, the greatest risk related to tobacco products is posed by the temperature which causes the release of nicotine into the aerosol [12]. The three most significant groups of products include:

1. traditional cigarettes: tobacco is burnt in the temperature of > 750 degrees Celsius; the tobacco smoke contains solid and gaseous particles, carbon monoxide and numerous carcinogens are inhaled in the process

2. *heat-not-burn* products, classified as novel tobacco products in Poland [13]; special disposable tobacco sticks are inserted in tobacco heating systems; their working temperature is around 300 degrees Celsius; tobacco pyrolysis occurs, but high-temperature combustion is avoided, there is no smoke, and the amount of toxic products is reduced by 90–95% as compared with conventional cigarettes [5, 14]

3. electronic cigarettes (e-cigarettes) – nicotine is released from a liquid at a temperature lower than 300 degrees Celsius, usually at the temperature of 150–180 degrees, with the exception being e-cigarettes with temperature regulation.

The number of the available heat-not-burn tobacco systems is quite small across the world (a dozen or so models in total), out of which only two have been registered in Poland. It would appear that it is not the structure of the heating devices that is important, but rather the specially prefabricated, standardized tobacco sticks.

The situation is quite different, though, when it comes to e-cigarettes that come in thousands of models. The estimated number of different devices available worldwide is ca. 10 thousand, while the number of different substances used in those systems is virtually impossible to count. In theory, anyone may produce their own "liquid," and frequently it does not contain nicotine at all. E-cigarettes thus serve as universal dispensers, and are not associated with any specific "liquid." They are sometimes used to dispense illicit drugs, legal highs, etc. As a consequence of such individual "experiments," their users may fall victim to severe poisonings [15].

There are considerable differences in the methods of registering novel tobacco products and electronic cigarettes. In Poland, for the tobacco heating systems, it is required to obtain a special decision issued by the Inspectorate for Chemical Substances (an agency that reports to the Ministry of Health), including a review of the available scientific studies on the toxicity, addictive properties and attractiveness of such devices, market research on the preferences of different consumer groups, and a risk-to-benefit ratio analysis. On the other hand, in the case of e-cigarettes, a mere notification is enough, with the required declarations attached. Moreover, in accordance with the 1995 Act on the

Protection of Public Health against the Effects of Tobacco Use, liquids that do not contain nicotine are not bound by the notification obligation. Practically speaking then, in the case of e-cigarettes, we seem to rely on the good will and ethical integrity of the suppliers. The situation is quite similar in other countries [15]. Therefore, it should be emphasized here that novel tobacco products, as compared with electronic cigarettes, are subject to an incomparably more stringent registration procedure. It remains inversely proportionate to the adverse events related to the use of both product groups [15]. Modern tobacco heating systems and e-cigarettes may take the form of complicated electronic devices, enabling accurate regulation of the physical and chemical parameters of aerosol generation, an in particular of the amount of nicotine delivered. It opens up the possibility of regulating nicotine dosage, which in turn brings about the possibility of individualizing and gradually reducing the alkaloid consumption [7].

WHY IS NICOTINE ADDICTIVE?

Nicotine "closes the information gates" in the central nervous system, and in the hippocampus in particular; that is part of the "information filter" theory [16]. The filtering of stimuli occurs at the level of P50 potentials, with the involvement of nicotine receptors, primarily α7 and α4β2. As a result, the feeling of information overload is reduced, one acquires a healthy distance to problems, and tensions are released. The sense of agency and competence in action is restored. A short-term euphoria and pro-cognitive effects appear. Thus, there is a typical positive feedback, wherein as a result of emotional, cognitive and social benefits, the smoker "learns" an addictive behavior, i.e. tobacco smoking. The more severe the psychological disorders are, and the greater the competence deficits, the higher the patient's susceptibility to self-medicate in such a way [17].

The route of nicotine delivery also has a significant impact on the clinical development of addiction; cigarette smoke contains not just nicotine, but other substances that increase the risk of addiction as well [18]. Additionally, conventional cigarettes inhibit the activity of monoamine oxidases (MAO), leading to enhanced activity of biogenic amines, while e-cigarettes and heated tobacco products do not cause significant MAO inhibition [19]. That would indicate a lower risk of developing an addiction to e-cigarettes and novel tobacco products.

Moreover, a separate addictive property of cigarette smoking is the behavioral ritual involved. Smoking takes place in important social situations, it is an element of different cultural codes. Depriving the smoker of their world of symbols and reinforcements will most likely hinder successful therapy. That would also explain why novel tobacco products and e-cigarettes, which embrace the social ritual, gain popularity, while products that only supplement nicotine (nicotine patches or chewing gums) do not prove sufficiently effective [9].

PHARMACOTHERAPY OF NICOTINE ADDICTION

The efficacy of nicotine addiction pharmacotherapy, vis-à-vis a 6-month-long abstinence, may be estimated as follows [20]:

- 14% placebo
- 27% nicotine – nasal spray
- 25% varenicline – 1 mg daily
- 25% nicotine – inhaler
- 25% clonidine
- 24% bupropion SR
- 23% nicotine – patches
- 23% nortriptyline
- 19% nicotine – gum.

Meeting additional conditions, one may hope for a slightly higher efficacy of anti-nicotine pharmacotherapy [20], by:

1. increasing the dose of medications, e.g. up to 2 mg daily of varenicline → 33%, nicotine patches > 25 mg → 27%
2. extending therapy duration, e.g. with nicotine gum > 14 weeks → 24%, nicotine patches > 14 weeks → 24%
3. administering combinations of different anti-nicotine drugs, e.g. nicotine patches with another drug, respectively:
   - + bupropion → 29%
   - + nortriptyline → 27%
   - + nicotine inhaler → 26%
   - + antidepressants (SSRI, SNRI) → 24%
4. stopping smoking abruptly with concurrent nicotine supplementation may lead to abstinence more effectively than gradual withdrawal of smoking combined with supplementation [21].

The above results, obtained in selected research groups, indicate limited final effects that are only slightly superior to placebo (14%) [20]. Additionally, a number of drugs that are commonly used in the treatment of emotional disorders and addictions, such as SSRI antidepressants or naltrexone, can hardly prove numerically superior to placebo (their respective efficacy rates: 14% and 7%) [20].

Recently, attempts have been made at using e-cigarettes and novel tobacco products in limiting smoking. An annual study involving the use of conventional nicotine supplementation methods as compared with e-cigarettes (*TEC study*) demonstrated a two-fold higher efficacy of the latter in maintaining a year-long abstinence (9.9% and 18%, respectively), coupled with a higher cost-effectiveness of e-cigarettes [7].

A multidisciplinary panel of university experts (psychiatry, oncology, rehabilitation, addiction therapy, and pharmacology) point-

ed out that an optimum novel anti-nicotine therapy should rely on two factors: the use of novel tobacco products, which enable health risks reduction (as compared with conventional cigarette smoking), and concurrent lowering of the levels of nicotine delivered (also made possible by the new tobacco systems) [22]. Additionally, it is possible to combine pharmacotherapy with psychotherapy, hypnosis and aversive methods.

Placing graphic warnings on cigarette packs only initially reduced the temptation to smoke, in around one fifth of smokers, which is not to say that it led to a complete cessation of smoking. Possibly, the images no longer act as a direct deterrent, but over the long run they contribute to the fact that cigarettes are no longer associated with an attractive lifestyle, as they were in the 1950s and 1960s, due to the popular ads that had a disastrous impact on population health [9].

WHAT ARE HARM REDUCTION PROGRAMS?

Harm reduction programs have been part of standard psychiatric interventions repertoire for decades. They consist in a substitutional administration of psychoactive substances. Accepting the fact of "controlled addition," we are capable of reducing potentially much greater health and social risks. Every program of the type also relies on the premise that the persons involved will eventually give up all psychoactive substances. The first historical example of such an approach was gradual barbiturate withdrawal. The drug intake was reduced very slowly, e.g. for a year, but the initial dose could even be increased. Today, we act in a similar way, when withdrawing benzodiazepines.

In 1999, methadone substitution therapy was approved in Poland for patients addicted to opioids. The method was initially considered controversial, as it did not do away with the primary addiction. However, health-related and social benefits of methadone use have been proven in practice. Thus, consecutive harm reduction programs were introduced less reluctantly, including naltrexone and nalmefene for the management of alcohol dependence, and different nicotine substitution products for nicotine addiction.

Harm reduction programs consist in administering:

- lower amounts of the same substance that caused dependence (e.g. nicotine patches, sprays or gums)
- or similar substances (e.g. methadone vs. opiates, cytisine vs. nicotine),
- or "substitutional" administration of substances that correct emotional disorders caused by psychoactive substance use (e.g. naltrexone vs. alcohol, antidepressants vs. addictions).

Such therapies are not aimed at a direct "cure," but instead, thanks to their stabilizing effects, they facilitate eventual cessation of psychoactive substance use. Harm reduction programs are associated with measurable benefits, such as improved/stabilized psychological condition, improved social/family functioning, continuation of schooling, maintenance of employment/studies, reduction in aggression/violence levels, decriminalization, prevention of prostitution, improvement of somatic states, reduction in the risk of infectious diseases, and a reduced number of deaths. They are applied in persons addicted to psychoactive substances, both legal and illicit.

The landmark FDA registration of the first *heat-not-burn* system opens up new possibilities of using tobacco heating devices in harm reduction programs [5].

LEGAL ISSUES

The provisions included in the 1995 Act on the Protection of Public Health against the Effects of Tobacco Use (hereinafter: the Act [13]) were modified on multiple occasions; in the amendment of 26 August 2016 [23] the terms "novel tobacco products" (NTP) and "electronic cigarettes" were mentioned as separate categories of tobacco products. Technological progress and new scientific studies as well as the legal and organizational changes across the world prompt one to review and revise the legal regulations.

The above mentioned Act needlessly associates novel tobacco products and e-cigarettes with the process of smoking ("It is forbidden to smoke tobacco products, including novel tobacco products and e-cigarettes"). Indeed, as emphasized before, it is crucial to differentiate between products in which the bioavailability of nicotine is actually associated with smoking (traditional cigarettes, pipes, cigars) and those products in which tobacco sticks or liquids ("smokeless" products: e-cigarettes, tobacco heating systems) are only heated. The distinction is of fundamental significance for the public health debate.

Additionally, provisions included in Article 5, section 1, of the Act define without the necessary accuracy the premises based on which different tobacco product groups have been specified. Thus, tobacco products include e-cigarettes (but not the liquids used in them), while e-cigarettes may not be "smoked," as they only serve as a vehicle for the delivery of specific substances to the body. In special cases, e-cigarette liquids may contain no nicotine whatsoever. *De facto* then, Article 5, section 1, does not put a ban on "liquid" use, but only restricts the use of the technical device employed for liquid delivery.

The term *novel tobacco products* should be considered as one that is not sufficiently accurate for an act of law, whose content

is supposed to serve as a legal basis for particular decisions. What is once novel, ceases to be such with time. The term was transposed from the Directive of the European Parliament and of the Council of 3 April 2014, implemented as of 20 May 2016 [24]. The current confusion surrounding NTP products stems from four different ways of defining them [13, 23]:

- NTP defined as all non-traditional products; following that definition, electronic cigarettes would also be considered as novel tobacco products (Article 2, item 11 [13]): "novel tobacco product – tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water pipe tobacco, cigar, cigarillo, chewing tobacco, snuff or snus"
- NTP defined as any tobacco product (that is not a traditional product), introduced after 19 May 2014 (Article 2.1.: "A novel tobacco product that is mentioned in Article 2, item 11, of the act amended in Article 1, in accordance with the content of the present Act, is a tobacco product placed on the market following 19 May 2014") [23]
- NTP defined as a special category of tobacco products, following the exclusion of traditional tobacco products and electronic cigarettes ("Article 5.1. It is forbidden to smoke cigarette products, including novel tobacco products and electronic cigarettes…" [13]); here NTPs are understood as heat-not-burn systems
- NTPs defined as a group of products subject to a separate registration pathway, and in particular different from the registration pathway for e-cigarettes (Article 11a vs. Article 11b [13]).

The legislative term *novel tobacco product* is not reflected in non-EU legal and medical systems. In a sense, the closest, but also a narrower, concept is the term applied in American legislation: modified-risk tobacco product (MRTP) [14]. The American concept of MRTP highlights the beneficial health characteristic of selected tobacco products. Thus, we observe different approaches on the part of EU and American legislators with respect to information flow: the former opt for avoiding differentiation [24S, Article 13], whereas the latter seem to favor differentiation of tobacco products based on their biochemical properties [14]. The EU directive is based on the premise that non-information protects users against potential disinformation. As a result, however, information on the actual parameters is not even present on the products in question (e.g. nicotine, tar or carbon monoxide content. Seen from a different angle, it would seem highly desirable and ethical to reveal the differences in tobacco product characteristics. In light of the new, independent studies, the level of carbon monoxide in the aerosol generated in novel tobacco systems is lower by 98–99%, and the level of aldehydes is 80–95% lower than in cigarette smoke [25, 26]. And then again, it would be best not just "to inform," but also "to educate" both patients and the medical staff within professional public health campaigns. It appears that putting a ban on information in the contemporary world is not possible, nor is it ethically appropriate.

It is worth analyzing the complex impact of legislative changes based on the amendment of 2016 [23]. Contrary to the intentions behind the amendment, hospitalization conditions worsened as a result for persons with psychological disorders, as smoking lounges (for traditional cigarette smokers) were reinstated (legalized) on in-patient wards. It was an attempt at sanctioning the fact that the complete ban on smoking had never been observed anyway. However, experience gathered in the years 2010–2016, when "smoking" was forbidden, but "smokeless" products were not, demonstrated positive results related to the use of the latter (Psychiatry Clinic of the Medical Faculty, Medical University of Warsaw; Psychiatry Clinic of the Medical University in Bialystok). By admitting the use of heated tobacco products and e-cigarettes, typical harm reduction programs were implemented in those centers, protecting patients against the effects of active and passive smoking. Presently, such programs are carried out in a systemic way in other countries, including the UK, where in 2019 e-cigarette kiosks were launched in two hospitals, for patients and visitors [27]; at the same time, traditional cigarette smoking is prohibited and punishable.

INTERNATIONAL SOLUTIONS

- USA. The American Food and Drug Administration (FDA) adopted a landmark decision on 30 April 2019, when registering the first NTP ("IQOS – tobacco heating system"), and justifying the decision in an official communication by stating that the system in question "produces fewer or lower levels of some toxins than combustible cigarettes." It was also emphasized that in the registration process, FDA took into consideration the new possibilities of reducing disease and death rates related to tobacco smoking, and "protecting public health," which FDA believes to be part of its mission. It was highlighted that the newly registered NTP contains reduced levels of many noxious substances, including carcinogens such as acrolein and formaldehyde (by a maximum of 95% and 91%, respectively), and the level of carbon monoxide remains the same as in the surrounding environment. It was also emphasized that a new possibility was opening up, i.e. transitioning from smoking cigarettes to using heat-not-burn products. As mentioned before, there is a special registration pathway in the American system for "modified-risk tobacco products" (MRTP) [14]. Importantly, legal provisions on MRTP had been drawn up much earlier than heat-not-burn products were introduced. They were in fact so stringent that in the years 2011–2018, none of the 19 products applying for approval received it. It was only in 2019 that the first such product was successfully registered

(it was the traditional Scandinavian "snus" for oral use). Presently, qualification procedures are underway with respect to the following: "very low nicotine content" cigarettes, further "snus" type products (also called "snuff" in the US), and granting the IQOS system the status of an MRTP, which is of greatest interest to all. Snus/snuff are niche products really, whereas IQOS is gaining world-wide popularity. The highly likely registration of IQOS as an MRTP, considering the statements included in the primary registration decision [5], and the speed of the current verification process [6], would mean that a product would be placed on the market that has been directly qualified as one fit for harm reduction programs.

- UK. The Public Health England executive agency (a public institution responsible for scientific counseling within the entire British healthcare system) postulates that one of the primary goals at present, given the fact that there are alternative products available, is doing away with all the products that involve "smoking" [18]. The agency emphasizes that it is not a purely toxicological issue, but what is also important is the fact that conventional cigarettes contain addictive substances other than nicotine that are released in smoke. It has also been noted that so far no tobacco product has been registered in the UK via the medical registration pathway (as in the case of the FDA registration in the US [14]). A list of postulates/concerns has been drawn up, to be resolved in the course of scientific studies. The research conducted to date has been quoted. It has been highlighted that only 1% of new "smokers" start from e-cigarettes (more in Spain: 1.2%), which fails to justify the fear of novel tobacco products. The data collected so far indicate a lower harmfulness of heated tobacco products as compared with traditional cigarettes. In 2016, the Royal College of Physicians [4] adopted three key recommendations related to the presence of alternative tobacco products on the market: 1. Cessation services should be adequately funded, and in clinical settings integrated systematically into routine health service delivery; 2. All existing and new policies with the potential to promote smoking cessation, particularly among disadvantaged groups, should be applied to their fullest extent; 3. A regulatory strategy should take a balanced approach in seeking to ensure product safety, encourage smokers to use e-cigarettes instead of tobacco, and detect and prevent effects that counter the overall goals of tobacco control policy. The harm related to the use of alternative tobacco products was estimated as unlikely to exceed 5% of that from smoking tobacco. Smoking was estimated to cost the NHS £2.5 billion a year, and the cost to the wider economy, including the cost of illness and absence from work and lost earnings, was estimated to be £9.4 billion a year.
- Japan. The use of e-cigarettes is forbidden in Japan. Thus, there is only market competition between traditional cigarettes and heated tobacco systems (there are three types of them on the Japanese market). Monitoring studies have not demonstrated an increased use of tobacco products in general, following the introduction of tobacco heating systems, but a gradual conversion from conventional cigarettes to the novel heated tobacco devices [28].

SUMMARY

Harm reduction programs offer a rational compromise aimed at protecting patients against the most severe health-related and social effects of tobacco. The tested novel tobacco products and electronic cigarettes (with verified ingredients of the liquids used) reduce the amount of absorbed noxious substances by 90–95% as compared with conventional cigarettes, which is an opportunity for active smokers to limit the catastrophic somatic harm involved. In the case of smokeless tobacco products, the risk associated with passive smoking is additionally minimized (even though not completely excluded [29]).

In developed countries, gradual conversion is observed from traditional cigarettes to NTPs and e-cigarettes. At the same time, in developing countries, over the years 1990–2017 [1], the number of deaths caused by tobacco smoking increased, e.g. in China by ca. 1 million deaths a year. In light of the scale of the problem, one is urged to agree with the British college of physicians, who postulate that all available harm reduction methods should be applied, including the use of new non-combustible tobacco products [4]. For persons who are unable to give up on nicotine use, a pragmatic elimination of the element of "smoking" is postulated, as smoking per se is the primary source of harm.

In preventative medicine, a lot of attention is paid to ensuring that novel tobacco products do not become a gateway to addiction in the population of young adults [30]. In that specific population, traditional anti-nicotine regulations are usually sufficient for proper prevention. What raises concern, though, is the fact of insufficient control over the online trade in e-cigarette liquids (whose ingredients often fail to be specified, contrary to the bans related to age), and the perception of "vaping" as a generational fad, not much different from consuming food products [15]. In some cases, the names of liquids themselves may actually suggest a link with a specific food item, e.g. e-cigarette liquid with a flavor of "ice candy" or "coconut cookies."

The available anti-nicotine drugs sold in Polish pharmacies are expensive, non-reimbursed, and only partially effective. 80% of people who take them in order to quit smoking, return to smoking within six months [20]. What is missing is a network

of clinics, different psychotherapeutic interventions on offer, and a convincing promotion of a lifestyle that does not require additional reinforcement in the form of tobacco smoking. Communication with the use of aversive stimuli (graphic images on cigarette packs) is only effective to a limited extent. A pragmatic approach to the use of new tobacco products that reduce health-related harm, brings us all closer to the final goal which is a complete renouncement of all tobacco products without exception [7].

An anachronistic and naïve conviction is still upheld that nicotine addiction (or addiction to smoking) is a result of a simple cognitive mistake, and that it is enough to explain it to active smokers, and use aversive methods to frighten off those more resistant to rational communication. However, nicotine addiction, just like any other type of addiction, results from the "benefit" that an individual draws from smoking, e.g. adaptation to a life in the conditions of civilizational overload.

The Polish stance is inconsistent, and so are the Polish legal regulations. The above mentioned reinstatement of smoking lounges in psychiatric wards, instead of the use of alternative tobacco products, may serve to illustrate the point. What is unacceptable is that in so doing, the medical staff is once again exposed to passive smoking. The market of commonly available (and easy to register) e-cigarettes in Poland is not sufficiently regulated, which leads to a situation, where the devices are sometimes used for "legal highs," which constitutes a direct threat to health and life. At the same time, regulations regarding novel tobacco products are disproportionately more stringent, and call for referential scientific studies, which would be well-grounded indeed, if we were to promote differentiation of tobacco products based on their higher or lower harmfulness (MRTP), following in the footsteps of the US or UK legislators. Presently, however, collecting such evidence only results from European regulations, whose significance is either misunderstood or not taken proper advantage of, as the two heated tobacco systems available on the Polish market are treated just like all other traditional tobacco products.

The only Polish epidemiological study did not demonstrate [31] that e-cigarettes and heated tobacco products had become a real alternative for cigarette smokers. Quite contrary, the use of cigars is more common in Poland than the use of e-cigarettes, and pipes are smoked more often than heated tobacco systems are used [31]. The study revealed that a considerable number of e-cigarette and heated tobacco system users (equal or higher than the number of the remaining active users) eventually cease all nicotine intake. In the case of traditional cigarettes, the proportion is different, with more people continuing to smoke than quitting smoking. That would mean that Polish smokers benefit from the potential of new tobacco products only to a limited degree, even though they might help reduce the risks involved. There are no pragmatic information programs in place. The experience gathered in developed countries does not indicate that modified-risk products increase nicotine use in the general population. They enter the market by way of decreasing the share of conventional cigarettes, as exemplified by Japan [28]. In the UK, only 5% of modified-risk tobacco products admit to not having smoked cigarettes before [9]. That goes to show that new tobacco products do not increase the incidence of smoking in the general population. The landmark American registrations [5, 14], confirming enhanced safety profiles of new tobacco products, also prompt one to introduce changes to the national information policy [32].

CONCLUSIONS

1. The downward trend of several decades has recently come to a halt in Poland as far as cigarette smoking is concerned.
2. Presently, we do not have an effective system on offer (a network of specialist clinics, inexpensive and/or reimbursed drugs/medical devices) for the management of people with nicotine dependence. Irrespectively of the institutional deficits, the available forms of treatment offer limited efficacy. Treatment plays a marginal role in the shaping of anti-nicotine policies.
3. Despite the convincing scientific research, we do not benefit from the possibility of directing smokers towards modified-risk tobacco products. Thus, we restrict the use of such instruments as harm reduction programs, dedicated to those addicted to smoking, in whom anti-nicotine therapies have proven ineffective. They remain exposed to the harmful effects of smoking. A multidimensional education campaign is needed for patients and for the medical staff, and an adequate public information policy regarding, inter alia, modified-risk tobacco products.
4. Without fully accepting the experience gathered in other countries, Poland does not presently conduct its own representative studies on the safety of tobacco products. No scientific studies are carried out on our own harm reduction programs in the management of nicotine dependence.

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