Adam Mazurek, Ph.D. (corresponding author)
Senior Specialist in Medicinal Products and Medical Devices, National Medicines Institute
p.mazurek@nil.gov.pl
Krzysztof Jop
Legal Adviser, National Medicines Institute

Legal issues in marketing of anabolic-androgenic steroids

Summary

This article provides an insight into the issue of illicit marketing of anabolic-androgenic steroids (AAS) in Poland. This risk attached to this phenomenon is particularly reflected in forensic opinions elaborated by the National Medicines Institute for the Police, prosecutor's offices, Border Guard and other agencies. The casework opinions concern AAS preparations not admitted to trading in Poland for various reasons, raw materials used in the production process, preparations admitted to trading, yet marketed in breach of the applicable provisions of law, and finally, falsified preparations. The article presents a range of the provisions of law, penalizing illicit marketing of AAS-containing products. The structure of criminal law provisions in Poland does not support the efficient reduction of AAS-containing products unlawfully introduced on the Polish market. As a rule, AAS-containing products are classified as medicinal products subject to medical prescription. The authors discuss the possibilities of applying alternative, more restrictive provisions of the Penal Code and other acts by the Police and prosecutors. For comparison purposes, a U.S. scheme of dealing with AAS marketing phenomenon was presented. The provisions of law in the U.S. are more restrictive as regards AAS, which are regarded as controlled substances equally with narcotics and dealt with by the Drug Enforcement Administration - a government agency responsible for combating drug-related crime.

Keywords anabolic-androgenic steroids, pharmaceutical raw materials, legal regulations, illicit marketing, sales without prescription, Internet, steroid abuse, health-related consequences

Introduction

While monitoring the illegal market for public health safety issues, the National Medicines Institute identified a substantial risk related to illicit marketing of anabolic-androgenic steroids. This risk has been particularly reflected in casework examination performed by the Institute on the request of the Police, prosecutor's offices, Border Guard and other institutions.

In 2013, the Institute issued 93 casework opinions concerning pharmaceutical crime. In total, 502 preparations and evidential items have been examined, among which the largest group (32,3%) involved anabolic-androgenic steroids (AAS) that were not admitted to trading in Poland for various reasons. Apart from these preparations, also other substances not admitted to trading have been seized, such as hormonal medicines, growth hormones, raw materials containing pure active substances and auxiliary substances used for production of anabolic-androgenic preparations, preparations admitted to trading, yet marketed in breach of the applicable provisions of law and finally, falsified preparations.

This publications presents the issues related to the marketing of AAS, mainly as they concern the applicable provisions of law.

The issue of anabolic-androgenic steroids is being addressed by the National Medicines Institute within the framework of the task no. 8.66 "The use of mass spectrometry and X-ray diffractometry for the analysis of substandard, illegal and falsified medicinal products and dietary supplements".

Definitions of anabolic-androgenic steroids, therapeutic effect and side effects

The following definitions of anabolic-androgenic steroids have been compiled based on the reports of the US National Institute on Drug Abuse [1, 2].

– Anabolic-Androgenic Steroids (AAS) are synthetic equivalents of a male hormone – testosterone. The first part of the name (anabolic) refers to the property of increasing muscle mass, whereas the second part (androgenic) to enhancing the development of masculine characteristics.
– AAS are used in the treatment of health problems associated with deficits of steroid hormones, such as impeded sexual maturation, hypogonadism [3] or diseases causing loss of muscle mass such as cancer or AIDS [4]. Due to risk to health or life posed by such preparations, they should be subject to medical prescription even when applied correctly without physician supervision. AAS are commonly used by athletes and bodybuilders to increase their strength and endurance, and to improve aesthetic values of their bodies.
– AAS are administered both orally and intramuscularly as well as in the form of creams or gels. The persons abusing AAS for non-medical purposes can take doses from 10 to 100 times higher than those prescribed by physicians for therapeutic purposes [2]. Athletes and bodybuilders use AAS in cycles rather than continuously, whereby the cycles last 8 weeks on average and are separated by pauses.

In his way, the AAS abusers try to avoid the side effects and allow their organisms to function properly. Continuous intake of AAS can decrease organism's tolerance to these substances and even lead to suspension of testosterone production [5]. The abusers use mixtures of different AAS, including non-steroid admixtures, in order to maximize their effect.

– Psychoactive effects of AAS are usually milder and different than those of other addictive substances. The main difference lies in the fact that AAS do not raise the levels of dopamine – a neurotransmitter responsible for a feeling of euphoria. Long-term use of AAS affects the distribution of certain substances such as dopamine, serotonin or opioids in the brain, which can influence the mood and behavior. AAS abuse can lead to aggression and other mental problems. Some of the abusers can experience an improved well-being, but on other occasions also mood changes, maniacal symptoms, irritation or even aggression expressing itself in the acts of vandalism, daring thefts or armed robberies. Other effects include paranoid jealousy, tendency to lie and lack of common sense resulting from the feeling of invincibility.

Using AAS can lead to addiction as confirmed by the data obtained from animal models. The abusers often continue taking AAS despite aggravating physical problems and negative effect on interpersonal relations, spending considerable sums of money on these preparations [5].

After discontinuation of the use of AAS, withdrawal symptoms can be experienced consisting in mood changes, fatigue, loss of appetite, insomnia or decreased libido. One of the most dangerous symptoms is depression which can lead to suicide. Some of the abusers may switch to narcotics in an attempt to alleviate the negative effects associated with the use of steroids. For example, a study on heroin abusers revealed that 9% of them had previously used AAS. Among this group, 86% had reached for opiates as a remedy for insomnia and irritation caused by AAS withdrawal [2].

The abuse of AAS can lead to serious or even irreversible health problems. Among the most severe consequences are kidney and liver damages, cardiovascular problems, including ventricular or atrial enlargement, high blood pressure, changes in cholesterol levels that increase the risk of heart attack or myocardial infraction even in young people. Other problems include the occurrence of acne, urinary retention or other diseases depending on age and gender. In males, AAS distort the production of hormones, thus causing both reversible and irreversible changes. Reversible changes include reduced sperm production and testicular atrophy, while irreversible changes encompass hair loss and gynecomastia. There is an increased risk of developing prostate cancer. Research conducted on bodybuilders showed that more than half of them suffered from testicular atrophy and gymecomastia [7].

When administered to females, AAS cause masculinization. The breasts shrink and the adipose tissue content drops. Symptoms such as facial hair growth, male pattern baldness, changes in menstrual period or its absence, clitoral enlargement and lowered voice timbre can be observed.

Table 1 Potential health problems associated with the abuse of anabolic-androgenic steroids (source: National Institute of Drug Abuse [2])

<table>
<tr>
<td rowspan="3">Endocrine system

Males:
- infertility
- gynecomastia
- testicular atrophy

Females:
- clitoral enlargement
- excessive hairiness

Both genders:
- male pattern baldness</td>
<td>Musculo-skeletal system
- lower height
- tendon ruptures</td>
<td>Skin
- acne
- cysts</td>
</tr>
<tr>
<td>Cardiovascular system
- heart attack, myocardial infraction
- right ventricular enlargement</td>
<td>Infections
- HIV/AIDS
- hepatitis B & C</td>
</tr>
<tr>
<td>Liver
- cancer
- miliary ecchymotic haemorrhages</td>
<td>Psychiatric effects
- suicidal thoughts
- manias
- delusions</td>
</tr>
</table>

In teenagers, the use of AAS can restrain body growth due to earlier skeletal maturation as well as it can accelerate sexual maturation.

Additionally, injecting steroid users are exposed to HIV and hepatitis B &C viruses. Some AAS preparations, in particular falsified ones, are manufactured under non-sterile conditions, which can increase the risk of viral infections. The abusers are also exposed to bacterial infections such as endocarditis. Studies on falsified AAS in the form of injectable liquid conducted at the National Medicines Institute in Warsaw have not revealed any bacterial or viral contaminations so far. This may be due to an oil-based formulation of AAS.

Marketing of anabolic-androgenic steroids (AAS)

In Poland, AAS preparations are classified as medicinal products as defined by the Pharmaceutical Law Act (PL) of 6 September 2001 due to their strong pharmacological effects [8].

Article 2 item 32 of the PL defines a medicinal product as ready to use product with specific formulation and objectively proven pharmacological properties, aimed at restoring, correcting or modifying bodily physiological functions. In addition, the definition is supplemented by subjective and independent condition of a market presentation of the product as having the property of preventing or curing a human disease. By this definition, the product not containing AAS, yet presented in accordance with the manufacturer's or marketing supplier's declaration, will be treated as a medicinal product.

For security purposes, if the product fulfills both the criteria for a medicinal product and for other type of product (e.g., dietary supplement, conditioner, cosmetic), the classification as a medicinal product is given priority – Art. 3a of the PL.

It needs to be pointed out that, as a rule, before being introduced onto the Polish market, each medicinal product needs to undergo a procedure of obtaining marketing authorization, which confirms that quality, efficiency and safety requirements have been met. Marketing authorization is applied for by the party bearing legal responsibility for a particular medicinal product. The authorization is granted by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products or, in the case of medicinal products authorized throughout the European Union in the framework of centralized procedure, by the competent EU authorities.

The information about marketing authorization appears on the product packaging. Medicinal products cannot be admitted to trading without authorization (with the exception of over-the-counter drugs, prescription drugs, semi-finished and direct import products).

Authorized medicinal products can be traded by strictly defined operators who were granted permission to conduct wholesale or retail sales activity by the National Pharmaceutical Inspection [8].

The authorization of medicinal products under national procedure in Poland is granted by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Warsaw, Al. Jerozolimskie 181C, 02-222, by way of administrative decision. The decision is issued upon application filed by the operator responsible for marketing of medicinal product.

Limitations in marketing of anabolic-androgenic steroids (AAS) in Poland resulting from criminal law

A basic provision imposing criminal liability for unlawful marketing of AAS-containing medicinal products is Article 124 of the PL. The criteria of a prohibited act specified in Art. 124 are fulfilled by marketing of the product or its storage with an intention of introducing onto the market without required authorization. Such misdemeanor is subject to fine, restriction of liberty or imprisonment for up to 2 years. Pursuant to Article 13 of the Penal Code[9], also the stadial forms of committing an offense are penalized, such as an attempt at marketing of medicinal products without authorization. It should be pointed out that Art. 124 only applies where the offense is committed intentionally.

It should be noted that the essence of the offense is illicit marketing of a medicinal product without marketing authorization applicable in Poland, issuable to the economic operator introducing the product. Therefore, in the first place it needs to be examined whether the particular product meets the definition of a medicinal product within the meaning of Article 2, item 32 of the PL, which is not always obvious. In the case when the introducing economic operator does not have the authorization valid in Poland, it may be necessary to appoint an expert who will assess the product, determine its classification under the provisions of pharmaceutical law and possibly conduct an analysis of the factual qualitative and quantitative composition of the product for compliance with manufacturer's declaration. It is particularly important in case of suspicion that the product might contain AAS.

A decisive factor for the classification of the product is the manner of its presentation by introducing operator. Relevant information includes the content of the label and leaflet, information on the composition and function of the product, and the manner it has been advertised on media. Based on these factors, the intents of the perpetrator in respect to the marketing of the medicinal product can be determined. Importantly, in the case of AAS- containing products for human

use, the bare information about the purpose of the substance (even without a detailed description) is sufficient for classification as a medicinal product, due to its strong pharmacological effect.

Another issue concerns a certain line of defense that the perpetrator may adopt, assuming the lack of awareness about committing an offense and the intention to introduce the substance that he did not consider a medicinal product. While facing criminal liability, the perpetrator may rely on the error of fact in regard to one of the constituent elements of the offense, that is to the nature of the introduced product. This constitutes an error of facts, regarding one of the statutory constitutive elements of the offense within the meaning of Article 28 § 1 of the Penal Code, which abolishes the premeditated nature of the act. The judgment of guilt is passed based on all evidentiary circumstances. It is therefore essential that sufficient evidence be collected as to avoid polemics about the possible error of fact. This includes commonly known characteristics of the product, the descriptions provided on the labels and leaflets as well as any other conduct of the introducing perpetrator; the involvement of an expert witness seems to be indispensable in this case.

Importantly, the possession of the AAS-based active substance considered as a pharmaceutical raw material within the meaning of Article 2, item 40 of the PL does not constitute a material act of the offense as set out in Article 124 of the PL, as the mere possession is not considered as preparation for introduction of the medicinal product. In the current legislative context, pharmaceutical raw materials containing AAS chemical compounds (until processed into ready-to-use product with specific pharmaceutical form) as a rule are covered by the provisions of the Act on Chemical Substances and Mixtures of 25 February 2011 (OJ No. 63, item 322) [10]. The preparation phase aimed at introducing a medicinal product without marketing authorization (with the exception of the storage with the intention of marketing, as set out in Art. 124) is also not penalized, under general principles of criminal law (Art. 16 § 2 of the PC). Specific regulations in this area pertain to psychotropic substances and narcotic drugs, within the meaning of the Act on Counteracting Drug Addiction of 29 July 2005 (OJ 2012, item 124, as amended) [11]. Article 56, item 1 of the above Act provides the following criteria of the offence: marketing of narcotic drugs, psychotropic substances or poppy straw, or participation in trading thereof, contrary to the provisions of Articles 33-35 and 37 of the Act. The infringement of the above provision results in a criminal penalty of fine or deprivation of liberty from 6 months to 8 years. Additionally, Article 57, item 1 penalizes the preparation phase of the offense described in Article 56, item 1 of the Act. Importantly, criminal penalty extends to all products, semi-finished products and raw materials containing the prohibited substance. The example given is of a pure academic nature as AAS do not appear on the list of narcotic drugs and psychotropic substances provided under the Act, which precludes the application of this particular Act to such substances.

Another relevant issue involves the meaning of a verb phrase introduced in Art. 124 of the PL, i.e. „introduces to the market" understood as a one-time activity. Such interpretation means that a person who distributes medicinal products introduced to the market by another person does not fall within the scope of the provision. Consequently, only whoever first introduced the prohibited substance to the market can be held liable in Poland. Successive actors involved in the supply chain bear no criminal responsibility even when they were aware that the product did not have marketing authorization (See (The ruling of the Supreme Court of 10 January 2007, file no. IV KK 426/0612 [12]). A simple legislative solution consisting in the clarification of the meaning of the verb phrase pertaining to the criminal offense (referred to in Article 124 of the PL) by rephrasing it to "any person who introduces to the market or distributes" would result in the extended criminal law protection.

The issue of unauthorized marketing of AAS-containing medicinal products focuses mostly around the practice of their falsification. Regretfully, there is *de lege lata* no definition of the falsified medicinal product (which should introduce the concept of a false representation of its identity, source or history). Considering a high level of social harm and serious risk to life and health caused by the falsification, it needs to be assumed that the existing law instruments available for protection against such practices are faulty and ineffective. The scope of criminal liability laid down in article 124 of the PL (which covers a certain part of the activities consisting in falsifying medicinal products) must be regarded as fragmentary, while the criminal penalties as not sufficiently severe, considering the level of social harm and comparing to other offenses of falsification with similar criteria, for example:

- falsifying or altering documents – criminal penalty of fine, deprivation of liberty or imprisonment from 3 months to 5 years, also the preparation phase to commit an offense is penalized (Art. 270 of the Penal Code),
- counterfeiting or forging currency - criminal penalty of a term imprisonment of not less than 5 years or of 25 years (Article 310 of the Penal Code).

In the case of a confirmed marketing of a medicinal product, the question should be posed about the place and legality of manufacturing. It is important to bear in mind that a different qualification of an offence can be adopted (as per Article 125 of the PC), inter alia, penalizing economic activity which involves the manufacturing or importing medicinal products without authorization. In the light of Article 2, item

42 of the PC, the manufacturing has a broad definition, encompassing any possible activities resulting in obtaining a medicinal product, including packaging, repacking and storing own products. Within the meaning of Article 2, item 7a of the PC, an import is any activity consisting in bringing a ready-to-use medicinal product from outside the European Union. In Poland, manufacturing or import authorizations are granted by the Chief Pharmaceutical Inspector. An offense consisting in engaging in even a single phase of manufacturing or importing is penalized by fine, restriction of liberty or imprisonment for up to 2 years. Illegal manufacturing sites for AAS-containing medicinal products, which lack conditions for conducting professional manufacturing process, can pose a threat to the natural environment as well as to health and life of persons residing nearby - a result of uncontrolled penetration of the waste generated during the manufacturing process into the environment. The above is a specific problem which remains beyond the scope of this article.

The possibility of pressing charges against the persons who unlawfully introduce AAS-containing medicinal products to the market is not only limited to the provisions of pharmaceutical legislation. A good example may be Article 165, § 1, item 2 of the PC which qualifies as a prohibited act provoking a direct threat to life or health, or a threat of inflicting a substantial property damage upon manufacturing or marketing of substances harmful to health, foodstuffs, other articles of every day use, or pharmaceuticals which do not meet applicable quality standards. The above offense is subject to a severe penalty – a term of imprisonment from 6 months to 8 years. Subsequent paragraphs of Article 165 provide for penalties for unintentional actions and a qualified offense resulting in multiple fatalities or serious injuries. Due to the fact that the provisions refer to causing a real and concrete threat by marketing of medicinal products, bringing charges against the perpetrator in this case requires a substantial workload devoted to collecting the evidence. Moreover, specialist expert opinions are required in the pharmacology/toxicology area assessing the possible effects of using a particular product. When dealing with illicit manufacturing or marketing of AAS-containing products, it always needs to be determined whether the provisions of Articles 165 § 1 of the PC and 124 or 125 of the PL could be applied cumulatively, particularly in the case when large quantities are introduced onto the market, the appropriate labels and information leaflets are not included in the packaging or when it follows from the description that the product is intended to be used for non-medical purposes, as a doping substance or to accelerate gaining body mass.

Additionally, it should be considered whether the criteria set out in Article 160 of the PC could be applied to legally describe a prohibited act of the marketing of AAS-containing products. The above article penalizes human exposure to direct of loss of life or serious bodily injury. The exposure is defined as creating a factual situation by the perpetrator, that can result in loss of life, serious injury or health disorder. Existence of an imminent danger means that in the situation created by the perpetrator, it is highly probable that the effects listed above will occur in the nearest future (see: The ruling of the Supreme Court of 29 November 1973, file. no. RW 902/73. [13]). This may be the case when the marketed AAS-containing medicinal product does not carry appropriate characteristics or carries instructions for use for other than medical purposes. A certain risk associated with the use of such products may also involve the absence of the supervision of a physician. In such a situation, an expert opinion is required that will evaluate a potential threat related to the marketing of such product. The perpetrator of the prohibited act specified in Article 160 § 1 is subject to a criminal penalty of a term of imprisonment for up to 3 years. If the perpetrator acts unintentionally, he is liable to deprivation of liberty or imprisonment for up to one year.

Certainly, the criteria of other prohibited acts related to illicit marketing of medicinal products should also be considered, such as involvement in an organized criminal group (Art. 258 of the PC) or the laundering of money generated by such crime (Art. 299 of the PC), however the detailed analysis of the above issue is beyond the scope of this article.

Incidentally, it is quite worrying that Poland, despite the reminder from the European Commission, has been postponing (since 2 January 2013) the implementation of the Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ EU L 2011, No. 174, p. 74 [14]). The provisions laid down in his Directive oblige Member States to implement a range of activities (including legislative activities, also in the area of criminal law) aimed at implementing proportional and adequate measures to protect the public from practices of falsifying medicinal products. In particular, the Directive defines falsified medicinal product as any medicinal product with false representation as to its identity, source or history.

Remarks on counteracting the illicit marketing of anabolic-androgenic steroids in the United States

For comparison purposes, some legal regulations applicable to AAS-containing formulations in the United States have been presented below.

The Anabolic Steroid Act 2004[15] was prepared in order to curtail the abuse of AAS by sportsmen and

teenagers. It is a restrictive Act, passed as a result of a long-term discussion which was initiated in the 80s. The EU Member States display a more liberal approach to the subject of AAS [16].

The Anabolic Steroid Act 2004 contains a body of penal provisions concerning the illicit marketing of AAS.

Anabolic-androgenic steroids were recognized in Schedule III [18] constituting an integral part of the 21 U.S. Code § 818 [17]. According to the legislator, the substances listed in Schedule III may lead to moderate or low physical dependence or high psychological dependence.

The provision 21 U.S.C. § 841 (b)1(D)[17] states that any person who knowingly or intentionally distributes the controlled substances listed in Schedule III, will be sentenced to a term of imprisonment of not more than 5 years. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years The penalties may be doubled if a person distributes drugs among minors (under 21 years of age) or in the vicinity of middle/high schools.

Schedule III-related drug offenses belong to crime groups 6-20, according to the USSG classification [19].

While most penalties for drug offenses listed in § 2D1.1 are graded, based on the weight of the object of the offense, a different approach was adopted in the case of the substances listed in Schedule III. For the offenses in this category, the so called “units” were introduced, whereby, in the case of AAS, one unit corresponds to 50 tablets or 10ml of injectable liquid. This means that in order to impose the same penalty, AAS must be present in larger quantity as compared to other substances of Schedule III. The difference may be 50-fold in the case of tablets and 20-fold for injectable liquids.

The format and contents of the Anabolic Steroid Act 2004 were based on previous legal regulations. In 1990, the Steroid Trafficking Act 1990 [17] was passed. An important regulation in the above Act was removing investigative and legislative powers concerning steroids from the jurisdiction of the Food and Drug Administration (FDA) and placing them under the Drug Enforcement Administration (DEA) as well as obliging the U.S. government agencies to include the issue of anabolic steroids in their drug prevention programs and guidelines. The subsequent bill passed by the Senate - Crime Control Act of 1990 (S.3266) [20], for the first time included the steroids in Schedule III and increased penalty for illicit marketing or possession with the intent to distribute of the growth hormone HGH (somatotropin) to 5 years of imprisonment, further doubled if the offense involved minors.

Also in 1990, the Drugs Working Group prepared the Steroids Report that was added to the Crime Control Act of 1990 (S.3266) as Appendix B [17]. The report addressed the issue of using the steroids in so called “cycles”, i.e., in a manner different from other Schedule III substances. Namely, AAS in the form of tablets or injectable liquids can be taken by the method of increasing and then decreasing weekly doses. On average, the duration of the cycle is estimated at 8 weeks with the average quantity of AAS taken during the cycle estimated at 196 tablets or 1150mg of the active substance in the injectable liquid. The cycle method for AAS intake was adopted from FDA procedures. Adaptation of the units towards AAS preparations without paying attention to the nature of active substance, formulation and potential created a dissonance between guilt and punishment. The Drugs Working Group proposed to solve this problem by applying the following conversion rate: 1 unit of AAS = 2 grams of any other Schedule III substance. At present, according to regulations of the USSG § 2D1.1, all Schedule III substances are expressed in units, by converting the weight of each of the drugs to its marihuana equivalent weight. The Drugs Working Group has finally assumed that during an 8-week cycle the individual user takes on average 5 units, whereas the dealer distributes 250 units among 15 people. According to data provided by the U.S. Anti-Doping Agency (USADA) (after USSC 2006 Report [17]), in 2004, a maximum penalty for a Schedule III - related offense (group 20) amounted to 33-41 months of imprisonment, imposed for the possession of 40000-60000 units. It was postulated that the penalty be doubled if the offense took place in the vicinity of the schools or sports facilities, i.e., most common sites of ASS distribution. In the U.S., the list of substances prohibited for use by athletes is continuously updated [21].

Around 1998, designer steroids and precursor steroids emerged in the U.S., which corresponded to the so-called “legal highs” available on traditional drug market. Frequent modifications of the chemical formulas of active substances present in such preparations allowed their sale as dietary supplements.

Availability of AAS is continuously monitored by the U.S. Governmental Accountability Office (GAO) [22].

The report by GAO indicated a range of problems the competent authorities encountered during controlling the distribution of AAS in the U.S. The problems relate to a massive importation of AAS preparations, the widespread use of Internet for placing orders and necessity to check the contents of enormous numbers of shipments at the borders by the Customs and Border Patrol Agency (CBP) in order to curtail the inflow of AAS. Another problem is connected with the relatively low level of penalties imposed on illegal AAS importers in accordance with the U.S. federal legislation.

In the pre-Internet era, AAS were smuggled into the U.S. and offered at the school premises or sports facilities, i.e., in the direct seller-buyer sales model [19], allowing easier control of such substances.

Numerous AAS preparations distributed in the U.S. originate from Mexico, Russia, Romania and Greece, which results from the availability in these countries as legal substances that can be obtained without prescription. AAS purchased in other countries are illegally smuggled into the U.S. Customer orders are collected over the Internet and phone. Upon receiving prepayment, the smugglers purchase AAS in pharmacies of the countries where they can be obtained legally without prescription. On some occasions, shipments containing purchased AAS are delivered to intermediaries who forward them to individual retailers.

Internet marketing of AAS

Currently, the Internet is a basic tool for illegal distribution of AAS, used for example for inquiring about the terms of transactions and placing orders.

Mail order sales of medicinal products in Poland are defined in Article 2, item 37aa of the PL Act [8]. Within the meaning of the Act on providing services by electronic means of 18 July 2002 [24], the sales are conducted basing on the sales contract concluded with the patient remotely, by email for instance. Mail order sales conducted by generally available pharmacies and dispensaries in Poland are restricted to OTC medicinal products not subject to prescription. Based on the declared qualitative composition, anabolic-androgenic formulations may only be available on prescription which excludes their legitimate mail order sales.

In practice, casework examinations performed at the National Medicines Institute most frequently concern foreign-origin AAS formulations seized from the illicit e-commerce market. The Internet offer also includes a certain amount of AAS-containing products originating in Poland.

A separate issue is importing AAS products subject to prescription into Poland for personal use. The possession of the above preparations for personal use is permitted in Poland. Pursuant to Article 68 of the PL Act [8], the importation of medicinal products for personal use in quantities not exceeding 5 smallest packaging units does not require permission of the Minister of Health. With regard to the products that are not authorized for marketing in Poland, there is no information available on the size of the smallest packaging unit and therefore, the determination of such is essential. According to the National Medicines Institute, it is the quantity marked on the smallest packaging unit available in retail. The examples of such units may be carton packaging containing five ampoules of 1 ml, carton packaging with one vial of 10 ml, carton packaging containing 25 tablets or two-three blisters of 10 tablets each.

U.S. e-commerce sales involve the payments via Western Union, PayPal, credit cards and bank transfers [22]. The shipments are delivered by postal or courier service.

According to special services officers, for some of the traffickers the sales of steroids and other synthetic substances may be the way to explore the channels of distribution for hard drugs such as cocaine.

The shipments delivered into the U.S. by postal and courier services are subject to control by CPB at 14 international postal agencies and 29 express dispatch agencies located throughout the country. While performing their duties, CPB officers take advantage of their practical experience, intuition and knowledge of the relations in the exporting countries. The shipments are selected, X-rayed, opened by the inspectors and searched. Certain difficulties with the identification of AAS are due to their concealment inside small electronic appliances, loudspeakers, blenders, alarm clocks or hollowed out books.

In order to effectively punish the traffickers, they must be identified and sufficient evidence must be collected by relevant authorities. On the other hand, the traffickers effectively use the anonymity offered by the Internet, making the identification impossible. Traffickers' Internet accounts are regularly changed which makes the identification cumbersome and time consuming. They communicate with the customers via email, whereby the addresses contain fictitious data and can be newly created and frequently changed using free email services. The investigative work is hampered by removing origin information from email messages. For example, Irish Hushmail service offers a client-to-client communication system within which the original IP (Internet Protocol) addresses are replaced by the provider's local IP addresses. Hence, when a trafficker residing in Florida sends a message to his customer in Virginia, the delivered message does not carry the trafficker's IP information but instead, it displays the Irish Hushmail address [22].

During the study assessing the efficiency of on-line pharmacies, conducted by the U.S. Govermental Accountabillty Office, 22 orders for AAS were placed over the Internet without presenting the prescription. It appeared that 45% of pharmacies completed the order [23]. Many of these pharmacies ignored the prescription requirement, while the others operated in countries where AAS are available without prescription such as Mexico or Thailand. The Drug Enforcement Administration provisions applicable in the U.S. oblige physicians to formally diagnose the patient. To make a diagnosis, a history of the disease and the examination results should be available to the physician who uses such data to determine optimal treatment. Some of the U.S. pharmacies comply with the above procedures of prescribing medications, while others offer on-line consultations in order to complete medical questionnaire, which may by followed by a telephone call. Such practices do not ensure the face-to-face physician - patient contact by defined by the law [23].

Illicit marketing of raw materials used for production of anabolic-androgenic steroids

A separate issue on a global scale is the legality of transporting or shipping of raw materials used for the manufacture of medicines, including active pharmaceutical ingredients (API) and auxiliary substances. An increasing problem is importing large quantities of AAS in the form of powder (active substance). The powders are used as raw materials in the manufacture of liquid products that are injected intramuscularly. The smuggling of powders is less amenable to monitoring than that of ready to use products.

The pure active substances - major components of medicines (including AAS) are imported into Poland as portions of powder (1kg, for instance) . Within the meaning of Art. 2, item 32 of the PL [8], such substances may not be regarded as "medicinal products" since the included shipping documentation does not contain a declaration by the manufacturer/recipient that the products have properties of preventing or curing human or animal diseases, or are administered with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions, by means of their pharmacological, immunological or metabolic activity. According to pharmaceutical data available, the powdered products contain synthetic human hormones with strong anabolic-androgenic activity. When the shipped substance is intended for preparation or manufacturing of medicinal products, it should be treated as pharmaceutical raw material within the meaning of Article 2, item 40 of the PL. Judging by the information on the seized powders and the accompanying documentation, such a purpose of the product is not evident. In view of the above, on the basis of the evidence gathered, such products should be regarded as chemical substances and subject to general applicable legislation, that is the Act on Chemical Substances and Mixtures of 25 February 2011 (OJ No. 63, item 322). Pursuant to the above legislation, marketing and possession of powders containing pure AAS are to be deemed legal provided, however, that the relevant business operator takes full administrative responsibility as well as civil and criminal liability for any infringements of the above act or universally binding provisions of law. If the operator placing a chemical substance on the market is an entrepreneur within the meaning of the Act on freedom of economic activity of 2 July 2004 (OJ L 2010, No. 220, item 1447 as amended) [25], more stringent requirements are applied regarding placing a chemical substance on the market (particularly as regards classification, labeling and notification of hazardous substance). In the case when these obligations are not fulfilled, the relevant provisions of the above act apply. However, the act does not apply to the substances imported into Poland in quantities and of the type indicating their intended use solely for personal purposes. As a rule, the importation of chemical substances into the territory of the European Union by a natural person is equivalent to introducing them to the market.

In the opinion of the National Medicines Institute and relevant knowledge on the subject, the only practical use for pure AAS substances is that as pharmaceutical raw materials - active substances in the manufacturing process of anabolic-androgenic medicinal products.

The "chemical substance" status of pure active pharmaceutical substances raises many controversies both among the operators engaged in marketing, manufacturing and control of medicinal products in accordance with the best interests of public health as well as among law enforcement authorities. When issuing opinion on raw materials made up exclusively of active substances used for productions of AAS, the National Medicines Institute includes the following note: "Importation of this product into the territory of Poland carries a risk that it will be used in an unauthorized manufacturing process of medicinal products without marketing authorization. The seized pharmaceutical active substance (pharmaceutical raw material) contained in this medicinal product may not be used without medical prescription and supervision, and its marketing may pose a threat to health or life of consumers".

Postal and courier deliveries also contain the substances that can be used as semi-finished products in the manufacturing process of food and medicines. These can include the components of tablet medicines or dietary supplements, food dyes or flavor additives. The above auxiliary substances are subject to the same provisions as the active substances, i.e. are conferred the "chemical substance" status.

In other countries such as the U.S., AAS preparations are listed among the controlled substances under the relevant acts such as the Anabolic Steroid Act 2004 [18].

Summary

The wording of the Penal Code and non-code law in respect of criminalization and penalization does not support an effective protection against illegal marketing of anabolic-androgenic steroids on the Polish market. AAS-containing products are as a rule classified as medicinal products with the category of availability: "Subject to medical prescription", with marketing authorization issued by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The problem lies in the fact that the pharmaceutical law penalizes with equal severity the unauthorized marketing of very strong and powerful products, and those which do not have such properties. Apart from the Act on Counteracting Drug

Addiction, there are no specific regulations available, protecting public health from uncontrolled marketing of products containing strong-acting substances, including AAS. The applicable provisions of the Penal Code, given their general scope, do not always allow bringing charges against the perpetrators.

In the U.S., AAS are regarded as controlled substances and they are dealt with by the Drug Enforcement Administration - a government agency responsible for combating drug-related crime.

The provisions of law in the U.S. are more restrictive as regards the above matters.

Another problem remaining still unsolved in Poland is that of illegal marketing of raw materials used in the production process of AAS. Such materials have the "chemical substance" status as they are not ready to use medicinal products. Penalization of the operators responsible for illegal marketing meets numerous legal obstacles. Moreover, there is a need to change legal regulations in a way that they become adequate to potential threat.

The article presented the issue of illicit marketing of AAS through Internet, which replaces the legally operating, licensed pharmacy wholesalers and retail pharmacy chains.

The problem of illicit marketing of AAS has become so serious as to have triggered the posting of warning messages addressed to teenagers and athletes on the website of the Municipal Police Department in Toruń [22].

De lege ferenda especially strict criminalization, in line with the provisions of the Act on Counteracting Drug Addiction, should be deemed appropriate in the case of illicit marketing of strong-acting substances, particularly AAS. Such an approach will provide a more efficient protection of public health in Poland.

The Polish Parliament is currently working on the government bill amending the Pharmaceutical Law Act and the Act on Counteracting Drug Addiction (Parliamentary document no. 2708). The works are aimed towards implementing the Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 obliging our country to take concrete actions, aimed at counteracting the marketing of falsified medicinal products [27].

Bibliography

1. National Institute on Drug Abuse Anabolic Steroids. National Institute on Drug Abuse. Update: July 2012, p.2. http://www.drugabuse.gov/publications/drugfacts/anabolic-steroids
2. National Institute on Drug Abuse Anabolic Steroid Abuse, Research Report, Aug.2006 p. 8 http://www.drugabuse.gov/sites/default/files/rrsteroids_0.pdf
3. Rabijewski M.: Farmakokinetyka i bezpieczeństwo preparatów testosteronu. „Przegląd Urologiczny" 2008, vol. 51, p. 13–22.
4. Bhashin S., Storer T., Javanbakht M. et al.: Testosterone Replacement and Resistance Exercise in HIV-Infected Men With Weight Loss and Low Testosterone Levels, "Journal of the American Medical Association", 2000, vol. 283, p. 763–770.
5. Information portal: www.steroid-abuse.org/index.htm
6. Maravelias C., Dona A., Stefanidu M. et al.: Adverse effects of anabolic steroids in athletes. A constant threat. Toxicology Letters, 2005, vol. 158, p. 167–175.
7. van Amsterdam J. et.al.: Adverse health effects of anabolic-androgenic steroids. Regulatory Toxicology and Pharmacology. 2010, 57, p. 117–123.
8. Pharmaceutical Law Act of 6 September 2001, OJ 2008, No. 45, item 271.
9. The Act Penal Code, OJ 1997, No. 88, item 553.
10. The Act on Chemical Substances and Mixtures of 25 February 2011, OJ 2011, No. 63, item 322, as amended.
11. The Act on Counteracting Drug Addiction, OJ 2005, No. 179, item 1485, as amended.
12. The ruling of the Supreme Court of 10 January 2007, file no. IV KK 426/0612.
13. The ruling of the Supreme Court of 29 November 1973, file. no.RW 902/73.
14. OJ EU L 2011, No. 174, p. 74.
15. Anabolic Steroid Control Act of 2004. https://www.govtrack.us/congress/bills/108/s2195/text
16. Prohormony, Internetowa encyklopedia PWN, Wikipedia 2014.
17. Steroids Working Group, United States Sentencing Commission, REPORT Washington DC, US Sentencing Commission March 2006. p. 32. http://www.ussc.gov/research-and-publications/working-group-reports/drugs
18. Schedule 3 (III) Drugs http://www.drugs.com/schedule-3-drugs.html

19. Placement of Sentences Under U.S.S.G.§ 2 D1.1– FY2010/2011 http://www.fd.org/docs/select-topics---sentencing/placement-of-sentences-under-u-s-s-g- 2d1-1-fy-2010-2011.pdf
20. Crime Controled Act No 3266 https://www.govtrack.us/congress/bills/101/s3266/text
21. The World Anti-Doping Code, The 2014 Prohibited List International Standard http://www.usada.org/uploads/substances/2014wadaprohibitedlist.pdf
22. United States Government Accountability Office, Report GAO-06-243R, Washington, November 3, 2005, pp. 12 http://www.gao.gov/assets/100/93845
23. McDonald Ch.L., Marlowe D.B., Patapis N.S. et al.: Nonprescription steroids on the Internet, Subst. Use Misuse. "NIH Public Access Author Manuscript" 2012, 47, p. 329–341.
24. The Act on Providing Services by Electronic Means of 18 July 2002, OJ No. 44, item 1204 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3252473/?report=classic
25. The Act on Freedom of Economic Activity of 2 July 2004, OJ 2010, No. 220, item 1447, as amended.
26. Municipal Police Department in Torun, Uważaj na sterydy anaboliczne! http://www.torun.kujawsko pomorska.policja.gov.pl/_portal/1204286607 47c7f48f62d58/Sterydy_anaboliczne stan na 15.05.2014 r.
27. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ EU L 174, 01.07.2011, p. 74).

Source

Table 1: [2]

Translation Rafał Wierzchosławski