



Short communication

Incidence of anabolic steroid counterfeiting in Brazil

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ABSTRACT

This retrospective study reports data obtained from the National Institute of Criminalistics of the Brazilian Federal Police Department (DPF) on 3676 anabolic products seized between 2006 and 2011. Anabolic androgenic steroids (AAS) were declared on the labels of 96.2% of the products. About one third of the products declared to be from Paraguay, and 14.3% from Brazil. Stanozolol, testosterone and nandrolone were the substances most declared on the labels. Package and qualitative chemical analyses (performed on 2818 products) found that 31.7% of the seized products were counterfeit, with an increase in the counterfeit detection rate during the period. Almost half of the fake products did not contain the declared substances, and 28.3% had only non-declared substances. Testosterone and its esters were responsible for 45% of the 582 cases of non-declared drug detection. Package analysis alone was responsible for the identification of 4.6% of all counterfeit products. These results indicate the need for a continuous effort by the government aimed at decreasing the availability of these products in the country.

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1. Introduction

The presence of counterfeit medicines on the international market was first mentioned at a World Health Organization (WHO) convention held in 1985 in Kenya [1]. A counterfeit medicine may be defined as a product that is deliberately and fraudulently mislabeled with respect to its identity and/or source, and includes products with the wrong ingredients, without active ingredients, with insufficient active ingredients, with fake packaging and/or high levels of impurities and contaminants [1].

The WHO once estimated that fake medicines were responsible for 1% of all medicine sales in developed countries and could reach 30% in some regions of Eastern Europe, Africa, Asia and Latin America [2]. Worldwide sales of counterfeit medicines could top US\$ 75 billion in 2009, a 90% rise in five years, but most studies only give a snapshot of the situation as counterfeiters are extremely flexible in the way they mimic products and avoid detection [3]. Any kind of medicine can be counterfeited, but common targets include antibiotics, hormones, analgesics, steroids, and antihistamines [1]. Data obtained from forensic reports issued by the Brazilian Federal Police Department (DPF) between 2007 and 2010 have shown that 69% of the counterfeits were

phosphodiesterase type 5 inhibitors (used for erectile dysfunction), and 26% were anabolic androgenic steroids (AAS) [4].

The AAS testosterone was first used in humans in 1937 to treat hypogonadism and associated conditions, and currently its main uses are for hormonal dysfunctions and aplastic anemia [5,6]. In the United States, there are around 3 million AAS users, and about 3% of young adults have admitted the non-medical use at least once in their lives of medicines containing AAS, mainly for esthetic and strength gain purposes [7]. In Brazil, the non-medical use of AAS has been declared by 9% of interviewees in Goiânia [8], 11.1% in Porto Alegre [9], and 19% in São Paulo [10].

The aim of the present study was to investigate the data collected on medicine products said to contain drugs with anabolic action seized by the DPF from 2006 to 2011.

2. Material and methods

This is a retrospective study describing the data obtained from the Brazilian Federal Police Department's (DPF) Criminalistics System database on pharmaceutical product reports issued between January 1, 2006 and December 31, 2011 by forensic experts at all DPF offices nationwide. These products were seized in criminal situations, mainly from smuggling or in raids on places where they were being stored to be sold.

First, a search using "anabolic" as the keyword was conducted in the database to identify the most frequent products and the most frequent AAS declared to be present in the products. The search was then repeated using the nine most reported AAS and the fifteen most reported products as keywords.

Information obtained from the DPF reports include the year and state where they were issued, the name of the products, the ingredients and country of origin stated on the labels, and final conclusions. When available, results of the chemical analyses and the analytical techniques used were also obtained. Qualitative chemical

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analyses were usually performed by gas chromatography coupled with mass spectrometer (GC/MS), infrared or ultraviolet spectrophotometry, and/or liquid chromatography coupled with a time-of-flight mass spectrometer (LC/TOF).

3. Results

Of the 6348 reports in the Criminalistics System database on pharmaceutical products issued by the DPF during the period of study, 923 (14.5%) contained at least one of the keywords considered in this study. The reports were issued in 21 of the 26 Brazilian states and in the Federal District, covering all five Brazilian regions. Almost one-fifth (18.5%) of the reports were issued in the state of Parana', located on the border with Paraguay, an area with major smuggling problems. The state of Sa~o Paulo, where the country's main airport is located, issued 13.5% of the reports.

The 923 DPF reports investigated in this study contained information on 3676 products that declared containing drugs with anabolic action, of which 3537 declared containing AAS, 99 declared containing clenbuterol, a β -agonist originally used as bronchodilator, 38 declared containing growth hormone, and 2 products declared containing gonadotropin. The number of anabolic products seized by the DPF increased sharply during the period under study, from 282 products in 2007 to 1468 in 2011 (Table 1). The DPF Criminalistics database was implemented in 2006, so the number reported for 2006 might not reflect the total number of anabolic products seized that year.

About one-third of the products were declared as coming from Paraguay and 14.3% from Brazil. Other common declared origins were Spain (9.6%) and the United States (7.6%) and 7.5% of the products had undeclared origin. Of the 145 different anabolic products found in the reports, ten of them (Stanozolol Depot, Durateston, Winstrol Depot, Winstrol V, Deca Durabolin, Stanozolol, Hemogenin, Nandrolone Decanoate and Ciclo-6) accounted for more than a half (52%) of all products seized. The most frequent AAS declared on the labels were stanozolol, testosterone and its esters, and nandrolone and its esters, accounting for, respectively, 29.6, 27.5 and 18.5% of the 3537 products from this class.

Qualitative chemical analyses were performed on 2818 products (76.7%), with almost all products seized in 2011 being analyzed (Table 1). Different drugs had different detection rates (detected/declared), ranging from 98.6% (clenbuterol) to 12.2% (boldenone and its esters); stanozolol was detected in 94% of the products declaring this compound (Fig. 1). Almost one-third of the 3676 anabolic products investigated were considered to be fake (31.7%), with an increase in the counterfeit detection rate during the period, reaching 38.8% in 2011 (Table 1). This increase was strongly correlated with the increase in chemical analyses ($r = 0.956$, $p = 0.003$).

Table 1

Products seized, products chemically analyzed and counterfeit detections during 2006–2011 by the Brazilian Federal Police Department.

| Year | Seized | Chemically analyzed | | Counterfeit detections | |
|-------|--------|---------------------|------|------------------------|------|
| | | n | % | n | % |
| 2006 | 41 | 1 | 2.4 | 1 | 2.4 |
| 2007 | 282 | 127 | 45.0 | 32 | 11.3 |
| 2008 | 474 | 180 | 38.0 | 99 | 20.9 |
| 2009 | 558 | 366 | 65.6 | 165 | 29.6 |
| 2010 | 853 | 748 | 87.7 | 300 | 35.2 |
| 2011 | 1468 | 1396 | 95.1 | 570 | 38.8 |
| Total | 3676 | 2818 | 76.7 | 1167 | 31.7 |

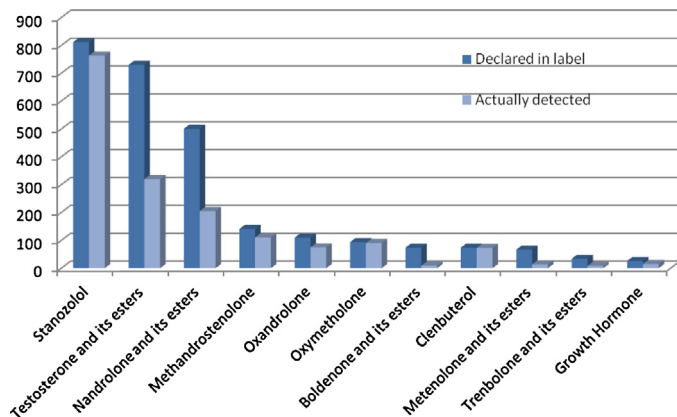


Fig. 1. Active ingredients declared on the product label and actually detected by CG/MS or LC/TOF (growth hormone).

Considering the 1167 fake products found in this study, 567 (48.6%) did not contain any active ingredient (for example, 11 "stanozolol" suspension products contained nothing but talc), 330 (28.3%) contained drugs that were different from those stated on the label, 188 (16.1%) declared an inexistent manufacturer or had fake packages, 66 (5.7%) did not contain all the drugs stated on the labels, and 16 (1.4%) contained additional drugs from those declared. In cases of non-declared drug detection ($N = 582$), the most frequent AAS involved were testosterone and its esters (45%), followed by nandrolone and its esters (18%) and prasterone (12%).

About 16.1% of the counterfeit products declared an inexistent manufacturer and/or had a fake package, and in these cases counterfeiting was easily identified by package analysis only. For



Fig. 2. Actual regular Hemogenin® package (left) and a fraudulent "Sarsa" package (right).



Fig. 3. (A) Original (left) and a fake (right) Hormotrop[®] flask, showing significant differences in the printing quality of the labels. (B) Fake Deca-drobo[®] flasks, with misspellings (Dacanoat instead of Decanoat, Proplonat instead of Propionat). (C) Stanzol[®] package with erasured label.

example, the product Hemogenin[®] was fraudulently commercialized under manufacturer names such as “Sarsa” with the appearance of the previous version of the original product (Fig. 2). Package analysis allowed the identification of 54 counterfeits among the 858 products that were not chemically analyzed, and which were replicas of an original product (and therefore could not be classified as “inexistent manufacturer”). Some examples are shown in Fig. 3.

4. Discussion and conclusions

The main strength of this study is the number of products investigated (3676), far larger than the number evaluated in most studies. Nevertheless, the percentage of counterfeit anabolic products found (31.7%) is similar to what has been described for the German and Belgian clandestine markets. In Germany, Musshoff et al. [11] found 35.7% of the 42 AAS products analyzed containing substances different than those stated on the label, or had no active ingredients. Similar results were obtained by Ritch and Musshoff [12], who evaluated 40 AAS-containing products (37.5% were fake), and Thevis et al. (35.4% of 48 products analyzed) [13]. Coopman and Cordonnier [14] found 33.8% of the 74 products analyzed in Belgium to be fake. Pellegrini et al. [15] found only two of the 15 AAS-containing products seized by the Italian Anti-Adulteration and Safety Bureau to contain what was declared on the label.

It should be noted that the counterfeit rate found in this study may be underestimated, as almost one-fourth of the products (23.3%) were not chemically analyzed. Additionally, the chemical analysis performed by the DPF was only qualitative, and counterfeiting due to the presence of the active ingredient at a different concentration from what was declared was not detected. Furthermore, as most of these products are foreign, neither the original packages nor information on them were available to aid in the package analysis.

In most countries, including Brazil, AAS are drugs that can only be sold with the presentation of a controlled prescription. However, a clandestine market at gyms and on the Internet has emerged to supply these products to those wishing to make non-medical use of AAS [11]. The users may assume that these products are weaker than the original and take a larger dose than recommended, which is a dangerous practice, as some fake products may contain as much as twice the stated content. Furthermore, the product may contain undeclared substances, which may lead to additional side effects. For example, women consuming a product that contains an undeclared AAS with high androgenic characteristics might have irreversible virilizing effects

[16]. In addition to the health concerns, counterfeiting may have major economic impacts on health systems and legal manufacturers, which suffer with the loss of confidence by the public [1].

The results found in this study indicate that the total amount of anabolic products available on the clandestine market is rising in Brazil, requiring continuous efforts by the government to decrease the availability of these products in the country.

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