

Official Medicines Control Laboratories (OMCLs)

Market Surveillance of Suspected Illegal Products (MSSIP)

MSSIP003: Illegal Anabolic Steroids

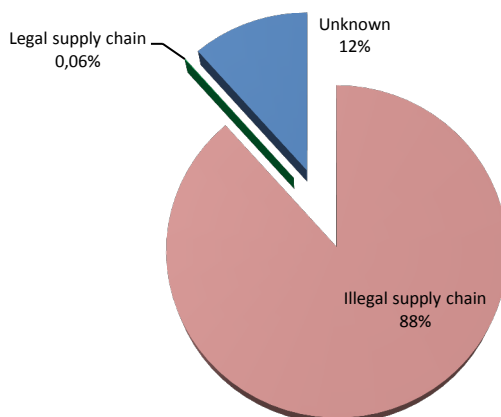
Summary Report

Introduction

As a third Market Surveillance Study of Suspected Illegal Products (MSSIP003), the OMCL Network decided to carry out a retrospective exercise on illegal anabolic steroids. These products are regularly tested by the OMCLs on behalf of their Competent Authorities and upon request by police, customs or other enforcement groups. The intention was to collect and compile pre-existing data for the study and to provide a picture of the situation at a defined point in time, which is nevertheless likely to be representative of the current market situation.

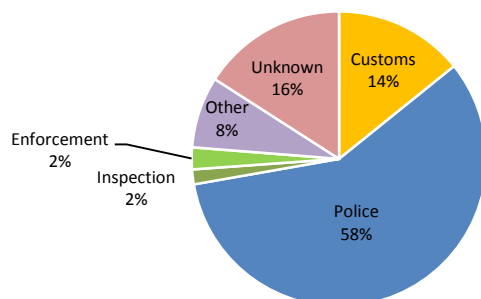
Participating laboratories were asked to provide data to the EDQM on the illegal anabolic steroids tested in their laboratory in the period between 2012 and 2014, and to report the presence of any declared and undeclared APIs (active pharmaceutical ingredients/active substances) in the samples, giving an estimation of the amount found where this information was available. They were also requested to provide information about the analytical method(s) used.

Seventeen OMCLs from 16 different European countries volunteered to participate in this exercise. Results were reported for more than 1600 samples. Most of these were obtained from the illegal supply chain; however, for about 12% of the samples, participants could not confirm whether they were obtained from the legal or the illegal supply chain.



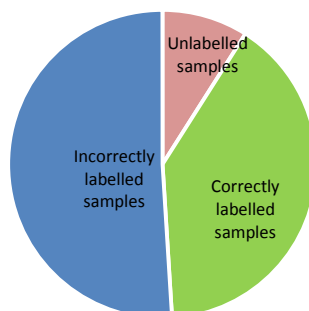
Origin of the tested samples

The origin of the tested samples was reported as follows:

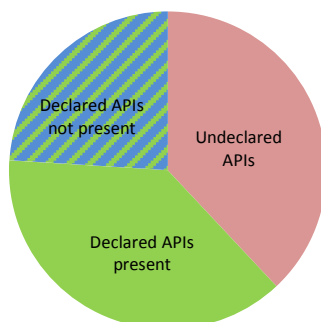


Declared and undeclared APIs in the samples

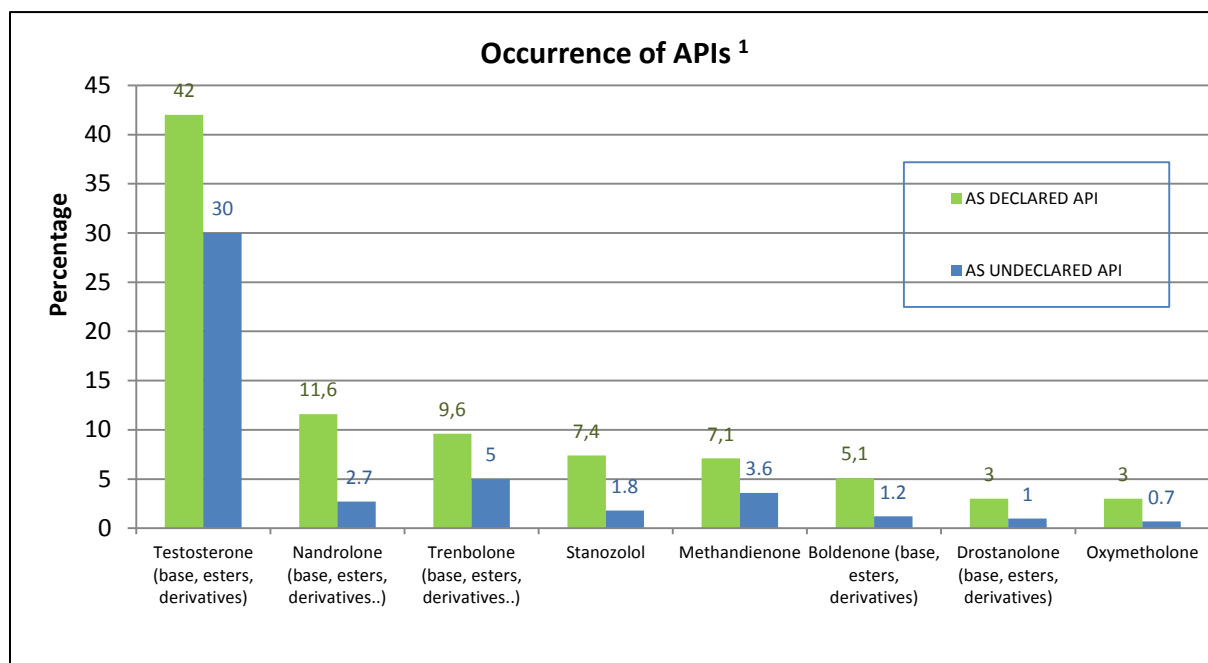
The percentage of unlabelled products was around 9%. Around 40% of the samples were correctly labelled while more than half of the samples were incorrectly labelled.



Around 38% of the products contained undeclared active substances. On the other hand, in about 24% of the samples analysed, the declared API(s) were not present.



In total, more than 80 different undeclared active substances were identified. A summary of the most frequently detected APIs is presented in the figure below:



1) For family molecules (base + esters + derivatives +..) the sum of the individual occurrences is displayed.

Most of the participants did not quantify the API(s) found in the samples, as this is not a requirement in their national legislation. Nevertheless, for those who did so, the estimated amounts of API present varied widely depending on the tested sample, and ranged from traces up to 50 mg/capsule or more than 250 mg/mL (liquid dosage forms).

Analytical methods used by the participants

The following analytical methods were used by the participating laboratories to identify and quantify the active substances present in the samples:

- Liquid Chromatography-Mass Spectrometry
- Gas Chromatography-Mass Spectrometry
- High-Performance Liquid Chromatography UV detection/Diode Array detection
- Fourier-Transform Infrared Spectrometry
- Quantitative NMR Spectroscopy
- Ultra-High Performance Liquid Chromatography-Mass Spectrometry
- X-Ray Powder Diffractometry
- Atomic Absorption Spectrophotometry

Conclusion

Illegal anabolic steroids are widely sold and used, in particular in sports, racing and bodybuilding scenes as performance-enhancing drugs.

The data presented above show that the quality of these drugs is defective as they are not produced under controlled manufacturing conditions; more than half of the samples analysed were not correctly labelled and contained one or more undeclared active substances, present at levels within – and even above – the therapeutic range.

Illegal anabolic steroids have adverse effects that could lead to serious health problems, sometimes with fatal outcomes. This is particularly true for products containing more than one anabolic steroid (almost 1/3 of the samples analysed) and those intended for parenteral use (injection).

Health risks to consumers are real and these findings show that further efforts are required to raise awareness among European citizens.