

Official Medicines Control Laboratories

Market Surveillance of Suspected Illegal Products (MSSIP)

MSSIP002: Dietary Supplements advertised as Sexual Potency Enhancers

Summary Report

Introduction

Twenty Official Medicines Control Laboratories (OMCL) from 17 different European countries participated in the second Market Surveillance on Suspected Illegal Products (MSSIP002). Participants were asked to analyse Dietary Supplements advertised as Sexual Potency Enhancers obtained from both the legal and the illegal supply chain, using methods of their choice, and to report the presence of any undeclared active pharmaceutical ingredient (API) found in the samples, estimating their amount whenever possible.

Origin of the tested samples

The origin of the samples tested within the study was the following:

- Enforcement (Customs, Police, Prosecutors, Finances);
- Pharmacy shops;
- Other “legal” shops including sex, food and herbal shops;
- Internet (legal and illegal);
- Competent Authorities (Health Authorities, Inspectorate, etc.);
- Others.

Overall, 522 sample batches were analysed; 180 (representing about 34% of the total) were obtained from the legal supply chain whilst the remaining batches (about 66%) were obtained from the illegal supply chain. A summary of the results reported is given below.

Findings

259 out of the 522 samples analysed in the study contained undeclared APIs; this represents 50% of the total. Considering only the products sampled from the legal supply chain, 82 out of the 180 samples analysed (about 46%) contained undeclared APIs.

Overall, more than 15 different undeclared active substances were identified in the samples by the participants, with the following estimated occurrence:

- Sildenafil and analogues were the most frequently found APIs, present in about 72 % of the samples containing undeclared APIs;
- Tadalafil and analogues: present in about 19% of the samples;
- Yohimbine: present in about 5% of the samples;

- Icariin and paracetamol: present in about 3% of the samples;
- Caffeine: present in about 1% of the samples;
- Vardenafil, dapoxetine, osthole, flibanserin, arginine, DHEA, berberine, sibutramine, chloramphenicol, metformin and naringin were found in less than 1% of the samples containing undeclared APIs.

The estimated amount reported per dosage unit (mainly capsules) was variable, going from traces up to 200 mg for sildenafil & analogues, 28 mg for tadalafil, 9 mg for yohimbine, 93 mg for paracetamol, 41 mg for caffeine or 63 mg for dapoxetine.

Conclusions

The second European Market Surveillance of Suspected Illegal Products MSSIP002: Dietary Supplements advertised as Sexual Potency Enhancers has ended. The group of products selected for the study is the most often falsified and sold in the legal and illegal market in the EU countries. Analysis of the results obtained demonstrates again the high level of competence of the OMCLs in testing illegal products, including products containing complex/elaborate herbal matrix and unknown composition. Simple analytical methods were used such as UV-VIS spectrophotometry as well as the significantly more complex UHPLC-MS-MS or NMR, leading to the discovery of many undeclared active pharmaceutical ingredients – mainly sildenafil and its structural analogues – thus confirming the scale of the threat. It should also be noted that the pharmaceutical formulation may have a large impact on health risks. For example, more rapidly soluble capsules and substances (analogues, salts, polymorphs) may boost the uptake and cause serious adverse effects (e.g., cardiovascular), which are not normally expected at that dose.

Due to the aim of this type of study (Market Surveillance of Suspected Illegal Products), two thirds of the dietary supplements analysed (66%) were obtained from the illegal supply chain and the samples selected were biased towards those suspected to contain undeclared APIs. As such, the results should not be taken as being a true representation of the European dietary supplement market. This sampling bias provides a compelling reason for the high percentage of samples with undeclared APIs. However, it should be noted that undeclared pharmacologically active substances were also found in samples from the “legal” supply chain (in this context, the legal supply chain is not limited to pharmacies but includes lifestyle and consumer goods shops and online sources). Health risks to consumers are real and these findings show that further effort is required both to improve the quality of products available to citizens and to raise awareness among consumers.