

Official Medicines Control Laboratories

Market Surveillance of Suspected Illegal Products MSSIP001: Slimming Dietary Supplements

Summary Report

Scientific advisor: Z. Fijalek (National Medicines Institute, Poland)

Introduction

Twenty-one OMCLs from twenty countries participated in the first Market Surveillance on Suspected Illegal Products (MSSIP001). Participants were asked to analyse Slimming Dietary Supplements obtained from both the legal and the illegal supply chains and to report the presence of sibutramine and analogues as well as any other undeclared active ingredient possibly present in the samples and the estimated amount thereof, using methods of their choice. They were also requested to report additional information such as the product name, the manufacturer, the origin of the samples, the dosage form and strength, the batch number, the expiry date, the labelled APIs and the analytical method used.

In total 370 batch samples were analysed. A summary of the results reported is given below.

Results for the samples from the individual markets

Origin of the samples

The origin of the tested samples was reported as follows:

- Internet: 58 samples (15.7 per cent);
- Enforcement officers (Customs, Police, Prosecutors, Finances): 214 samples (57.8 per cent);
- Pharmacy shops: 41 samples (11.1 per cent);
- Body building shops/Asian shops: 32 samples (8.6 per cent);
- Miscellaneous (subcontractor, USA prod., mail, others): 14 samples (3.8 per cent);
- Unknown: 11 samples (3.0 per cent);

It was not always clear whether the products analysed should be considered as having been sampled from the legal or from the illegal supply chain, in particular in the case of products sampled in body building shops or from the Internet.

Undeclared APIs found in the samples

At least one undeclared active pharmaceutical ingredient (API) was found in 173 products (47 per cent of the batch samples analysed), including 3 products sampled in pharmacy shops.

About 40 different undeclared active substances were identified by the participants, with the following occurrence:

- Sibutramine and sibutramine analogues were the most frequently detected APIs (found in 126 samples, representing 34 per cent);
- Phenolphthalein was found in 31 samples (8.3 per cent);
- Caffeine was found in 24 samples (6.5 per cent);
- Sildenafil and analogues were found in 13 samples (3.5 per cent);
- Metformin was found in 6 samples (1.6 per cent);
- Fluoxetine and rimonabant were found in 5 samples (1.3 per cent);
- Yohimbine, ephedrine/pseudoephedrine, fenfluramine, propranolol and nifedipine were found in 4 samples (1.1 per cent);
- Sennosides (A/B), lignocaine and thyroid hormones were found in 3 samples (0.8 per cent);
- Hydroxyanthracene glycosides were found in 2 samples (0.5 per cent);
- Diazepam, hydrochlorothiazide, orlistat, benzylpiperazine, theobromine, vitamin E, serotonin, piperin, bisacodil, synephrine, diethylpropion, chromium picolinate, carnitine, nicotinamide, chlordiazepoxyde, choranaline, quinine and progesterone were found in one sample (less than 0.3 per cent).

When herbal drugs appeared on the label of a product, it was not always clear whether the active substances found in the sample which are natural components of these herbal drugs (e.g. caffeine, quinine, synephrine, capsaicin or asarinine), should be considered as declared or undeclared substances. It appeared that this could depend on national interpretations and therefore varies from one country to another.

The estimated amount reported per unit (mainly capsules) was variable, for example traces up to 30 mg for sibutramine, 13 mg for fluoxetine and synephrine, 94 mg for phenolphthalein, 118 mg for metformin, or 120 mg for caffeine.

Analytical methods used by the laboratories

The following methods were used alone or in combination by the participants for the analysis of the samples:

- IR (one laboratory)
- TLC (one laboratory)
- UV-Vis (one laboratory)
- HPLC-UV; HPLC-DAD (thirteen laboratories)
- HPLC-MS (ten laboratories)

- UHPLC-UV; UHPLC-DAD (six laboratories)
- UHPLC-MS (two laboratories)
- GC-MS (eight laboratories)
- NMR/qNMR (one laboratory)
- MS-QTOF (one laboratory)

Comments from the scientific advisor

The first European Market Surveillance of Suspected Illegal Products MSSIP001: Slimming Dietary Supplements has just ended. It was preceded by multiple discussions within the network: which products should be chosen for testing, how should sample collection and testing be carried out, which information is to be prepared to share with participating labs, what to search for and which methods to use in testing. As a result, slimming products were chosen, leaving the choice of collection procedures and analytical methods to each laboratory based on their thorough experience. Analysis of the obtained results demonstrates the network's labs excellent preparation towards testing illegal products, including products containing complex/elaborate herbal matrices and unknown composition. Simple analytical methods were used such as TLC or UV-VIS as well as the significantly more complex UPLC-MS or NMR, leading to the discovery of many undeclared active pharmaceutical ingredients – mainly sibutramine and its structural analogues – thus confirming the scale of the threat.

As a conclusion it should be made clear that nearly one in two slimming products (47 per cent, mainly declared as dietary supplements) analysed in the study, sampled from the illegal and the legal supply chain, are potential health risks to consumers. One can only hope that European bodies in charge of public health will – in the light of these findings – take appropriate measures to ensure better oversight of products available to EU citizens and raise awareness among consumers.