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Short communication

Illegal medicines in Europe: hazards and analysis

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Introduction

The trade and distribution of illegal medicines is a lucrative business that, despite regional differences is a worldwide problem (World Health Organization, 2024). Within illegal medicines, different categories can be distinguished: substandard, unlicensed or unauthorized and falsified medicines. The first category are legally produced medicines with quality deficiencies and so should have been destroyed. Unlicensed and unauthorized medicines, are products that may be legal in the country of origin, but not authorized for market distribution in other countries. Also here the imitations, products not copying the authorized products, but sold as often cheaper alternatives, are comprised. Finally, falsified medicines are defined as products that deliberately or fraudulently misrepresent their identity, composition or origin. Here, illegal copies and medicines in disguise have to be distinguished. The latter are dietary supplements, cosmetics, food or other consumer products that contain undeclared active pharmaceutical ingredients (API). These products pose high health risks, since consumer and health care workers are unaware a medicine is taken, possibly causing secondary effects or interactions with already existing therapy (Deconinck, 2025).

From a laboratory point of view the most structured investigations in the context of illegal medicines are performed by Official Medicines Control Laboratories (OMCL), collaborating in the worldwide General European OMCL network (GEON).

This paper gives an overview of the hazards identified by the Belgian OMCL and focusses on the results obtained from the collaborative studies (Market Surveillance Study on Illegal Products (MSSIP)) organized throughout the GEON network.

Materials and methods

Set-up of MSSIP studies

Each MSSIP study focusses on a category of products, based on indication or presentation, selected according rising trends observed by one or several members within the GEON network.

Data collection on analyzed samples, usually consists of a retrospective and prospective part and encompasses the origin of the samples and the declared and found APIs, which may be complemented by quantitative or other results.

Sample and data collection

Samples, subject of the different MSSIP studies were collected through the national channels of each individual OMCL.

Samples, subject of the national investigations by the Belgian OMCL were all samples seized by the inspection services of the Federal Agency for Medicines and Health Products (FAMHP).

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Results and discussion

During analysis of suspected illegal medicines at the Belgian OMCL, issues with dosage, absence of APIs or presence of wrong APIs, contamination and galenic formulations could be observed. Underdosage could lead to ineffective therapy and in the case of, for example, antibiotics even to the emergence of bacterial resistance, while overdosage can lead to secondary effects and intoxications. The absence of an API could be a best scenario for example in the case of falsified GLP-1 inhibitors sold for slimming, but will often result in ineffective therapy. The wrong API could lead to fatal accidents, e.g. the presence of insulin in fake GLP-1 inhibitor injectables, while the presence of untested designer molecules could cause unexpected effects. Contaminations, like cross contaminations with unwanted substances or microbial contamination, often occur due to the use of low quality primary substances and the absence of good manufacturing procedures. Finally galenic issues, as absence of uniformity of content and non-compliant dissolution profiles were observed. These issues could lead to therapeutic failure or in the case of antimicrobials in emergence of resistant strains.

The GEON wide MSSIP studies reflect the occurrence of illegal products, circulating mainly on the non-regular market. The first MSSIP focused on slimming aids and comprised 173 samples, positive for at least one API. The most popular APIs were sibutramine and its analogues and phenolphthalein. The MSSIP002 study on potency enhancer showed 259 positive for an API with the PDE-5 inhibitors (sildenafil, tadalafil and their analogues) and yohimbine as the most encountered. MSSIP003 on anabolics comprised 1600 samples. Testosterone esters and analogues were by far the most popular APIs. The next two subjects were selected based on representation and composition. MSSIP004 was focused on medicines in disguise, where data on 297 samples was collected. 82% of these samples were sold as potency enhancers. The next study dealt with non-INN molecules and counted 1104 samples. The top 5 encountered product categories were anabolics, research peptides, PDE-5 inhibitors, SARMs and drugs modulating the central nervous system (Deconinck et al., 2021). Following these results, MSSIP006 studied SARMs. Interesting here is that 65% of the included products were sold as “looking like a medicine”. The top 5 molecules encountered were ibutamoren, ligandrol, ostarin, cardarine and Andarine (Barrios et al., 2025). MSSIP007 targeted the incidence of Nootropics. 159 samples were reported and half of them was sold as dietary supplement. Melatonin, modafinil and L-dopa were the API for more than 50% of the samples (Vanhee et al., 2025).

Conclusion

To conclude it has to be said that pharmaceutical crime is still growing and vigilance is important, especially by health care workers. Intoxication and treatment failures may be due to the use of falsified medicines or medicines in disguise.

Moreover it is important to monitor the market and follow up emerging trends. Results as these of the MSSIPs are valuable for awareness-raising and prevention.

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