General European OMCL Network
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
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Official Medicines Control Laboratories (OMCL)

Market Surveillance of Suspected Illegal Products (MSSIP)

MSSIP004: Medicines in disguise

Summary Report

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Introduction

For the fourth Market Surveillance Programme on Suspected Illegal Products (MSSIP004), the General European OMCL Network decided to carry out a retrospective study on "medicines in disguise". According to information collected over a two-year period (2015–2017) from the Know-X database – an IT tool used to record information on cases of falsification of medicines and other medical products – 32 % of the reported cases corresponded to products not presented as medicines, but as food supplements, cosmetics, medical devices, etc. In total, 53 % of these non-medicinal products were found to contain undeclared active pharmaceutical ingredients (APIs) described in the Anatomical Therapeutic Chemical (ATC) classification system – International Non-Proprietary Name (INN) list. As they were not cases related to medicines by presentation, they fall out of the scope of market surveillance of medicines in Europe.

Scope of study

Participating OMCLs were asked to provide data on medicines in disguise tested in their laboratory between January 2016 and September 2018, and to report the presence and the quantities of any undeclared API in the samples to the EDQM.

It was agreed that any medicine in disguise which contained undeclared APIs from the ATC - INN list included in authorised medicines on the market of the country where the product was sampled would be within the scope of the study. The detected API(s) should be present in the product in a quantity equal to or greater than the quantity of API in an authorised medicine (reference product).
The agreed evaluation criterion regarding the quantity of detected APIs was: results greater than or equal to 90 % of the lowest API quantity in an authorised medicine will be evaluated as "findings" and will be reported.

Seventeen OMCLs volunteered to participate in this programme.

Selection of samples

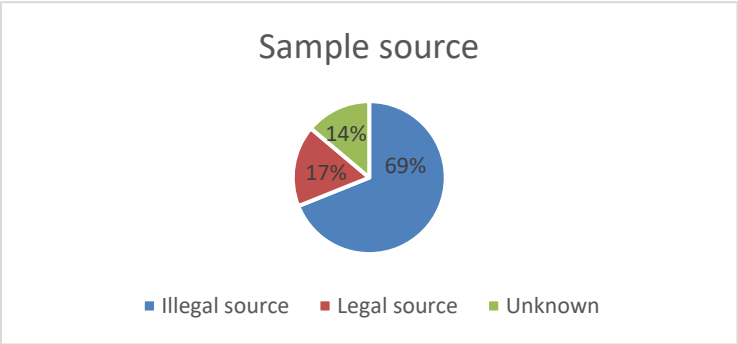
Results for 361 samples were reported; 17 % (64) were excluded from the study for the following reasons:

- The identified quantity of API was not in the specified range (below 90 % of the lowest API

quantity in an authorised medicine) (28 cases);
- The identified API was not on the ATC – INN list (e.g. PDE-5 inhibitor analogues) (14 cases);
- There was no equivalent product on the market (6 cases);
- Insufficient information concerning the API content (16 cases).

Origin of tested samples

Most of the samples were obtained from the illegal supply chain. For about 14 % of the samples, participants could not confirm whether they were obtained from the legal or the illegal supply chain.



Overall, the origin of the tested samples was reported as follows:

- **Targeted Police/Customs Operation: 134**
- **Commercial shop: 29**
- **Internet: 18**
- Distributor/Wholesaler: 9
- Secondary packaging and labelling site: 7
- Alternative practitioner: 4
- Beauty centre: 4
- Retail Pharmacy: 3
- Other: 2
- Darknet: 2
- Parapharmacy: 1
- Street: 1
- Unknown: 83

Providers of tested samples

The providers of the tested samples were reported as follows:

- **Inspector: 203**
- **Law enforcement (Police, etc.): 52**
- **Customs: 33**
- Other: 5

- Unknown: 2
- Health professional: 1
- Patient/Private person: 1

Product types of tested samples

The following main product types were reported:

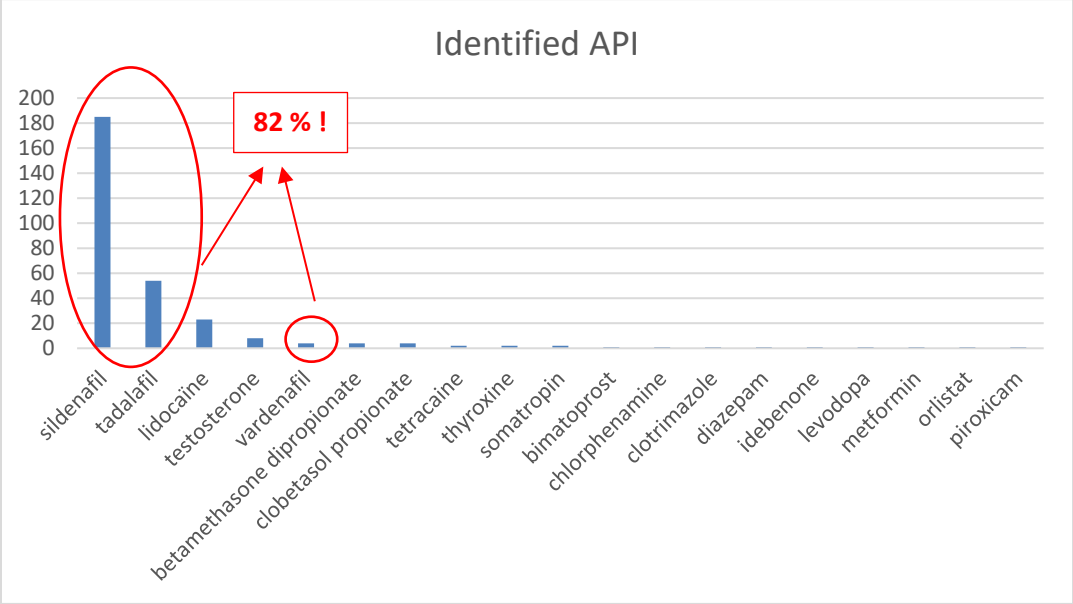
- **Food supplements: 127**
- Sex accessory: 113
- Other: 33
- Cosmetics: 7
- Steroids: 6
- Tattoo Ink: 3

Dosage forms of tested samples

The following main dosage forms were reported:

- **Tablets: 148**
- **Capsules: 81**
- Cream/ointment: 14
- Spray: 14
- Solution liquid: 11
- Powder: 8
- Solution for injection: 8

In total, 19 different active substances were identified. The graph below shows that APIs used for erectile dysfunction represent the majority of medicines in disguise (82 %) tested in this programme:



Conclusion

Medicines in disguise are widely sold and used. It is important to note that samples from only 17 OMCLs were collected from their national markets and reported in this study. It can reasonably be assumed that far more medicines in disguise are illegally available on the European market.

Sixty-nine percent of the tested products were sampled from illegal sources (e.g. provided by police or customs authorities) and 17 % from legal sources (e.g. sampled from commercial shops, beauty centres, distributors).

The available data demonstrate that the most frequent medicines in disguise are "**food supplements**" presented as tablets or capsules.

The principal indication of these products is "erectile dysfunction". In total, 82 % of the tested products contained sildenafil, tadalafil or vardenafil. Thus, erectile dysfunction represents an important business model.

Health risks to consumers are real, as APIs present in these products are not always declared on the label. APIs found are normally dispensed under prescription and may have adverse effects that could lead to serious health issues. In addition, API contents varied widely and in some cases were found to be much higher than in the reference product with the highest authorised dosage (e.g. 345 mg sildenafil/tablet).

In addition, in this report only cases in compliance with the acceptance criteria were taken into account. Products, containing a quantity below the limit of 90 %, were also reported. Many of them represent a threat for consumers as they contain potent APIs (e.g. bisacodyl, oxytetracycline, fluoxetine) which can have a physiological effect even at lows quantities. In some cases, e.g. for low dosed antibiotics, this can even lead to drug resistances.

According to Directive 2001/83, as medicines in disguise are Medicinal Products by function, they could be considered as Falsified Medicinal Products. However, in a number of European countries and also for the EU Authorities, medicines in disguise presented as food supplements fall under food legislation. In addition, food supplements are not tested in the same manner in market surveillance programmes as this is the case for medicines.

All findings show that further efforts and a better control of food supplements and other products, such as certain cosmetics and medical devices, are required. It also appears to be important to raise awareness amongst citizens about the risk of these products.

More than 80% of the samples analysed in this study were *de facto* Falsified Medicinal Products, which underlines the seriousness of the problem.