

# A Survey on Illegal and Counterfeit Medicines for the Treatment of Erectile Dysfunctions in Italy

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## ABSTRACT

**Introduction.** In developed countries the phenomenon of pharmaceutical counterfeiting is steadily increasing through the illegal and the Internet market. Medicines for the treatment of erectile dysfunctions containing phosphodiesterase type 5 inhibitors (PDE5) are especially prone to falsification.

**Aims.** To obtain evidence of the health risks for patients taking these products and to provide useful information to general practitioners and specialists in sexual medicine.

**Methods.** First the samples were visually inspected and then analyzed to get information about their identity and quality.

**Main Outcome Measures.** A survey on the PDE5 medicines analyzed by the Italian official medicines control laboratory between 2005 and 2011 was performed. All the analyzed medicines were gathered from the Italian illegal market (seizures by police forces) or were bought from illegal online pharmacies.

**Results.** The study revealed that 24% of the analyzed samples were counterfeit and 54% were illegal medicines. In 12% of the cases an intermediate classification (*illegal/counterfeit*) was assigned. Only 7% of the samples were original. Moreover, the examination of the packaging evidenced potential risks: outer and immediate packaging missing; inconsistency between the carton box and the blister as regards the expiry date and/or the batch number; expiry date or manufacturer's name or country missing.

**Conclusions.** In 19% of the samples a potential health risk for patients was identified due to either the presence in the sample of more than one undeclared PDE5(s) or an amount of the active ingredient higher than that declared (up to 190% of the maximum dose) or to the presence of potentially dangerous excipients of non-pharmaceutical origin or quality (e.g., gypsum or non-purified talc). **Gaudiano MC, Manna L, Rodomonte AL, Bartolomei M, Bertocchi P, Gallinella B, Antoniella E, Muleri N, Civitelli G, Alimonti S, Romanini L, Rufini L, and Valvo L. A survey on illegal and counterfeit medicines for the treatment of erectile dysfunctions in Italy. J Sex Med 2012;9:2130–2137.**

**Key Words.** PDE5 Inhibitors; Counterfeit; Illegal Medicine

## Introduction

Until recently, counterfeit medicines were considered a serious health threat only for people living in developing countries, where drug market surveillance is often very poor or missing entirely. More recently, market globalization and the Internet has opened new scenarios

and posed new risks for public health, also now in developed countries, where the increasing practice of purchasing medicines from online pharmacies or from the illegal market (e.g., gyms, sex shops, ethno shops) is exposing more and more people to the risks related to the consumption of illegal and/or counterfeit medicines [1–19].

The World Health Organization (WHO) defines a counterfeit medicine as one that is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and may include products with correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredient or with fake packaging [20]. An illegal medicine is one that is sold without marketing authorization. An illegal medicine could be legal in other countries.

The practice of buying medicines over the Internet, or from other illegal distribution channels, shows no trace of abating. This in spite of many educational campaigns aimed at raising awareness on the risks and despite all the efforts put in combating the phenomenon by the Food and Drug Administration, the Council of Europe, the European Medicines Agency, the European Directorate for the Quality of Medicines & HealthCare, and the WHO by means of its special anticounterfeiting task force International Medical Products Anti-Counterfeiting Taskforce (IMPACT) [21–24]. The simple reason for the apparent failure of these efforts is that medicines bought from illegal sources have considerably lower prices and do not require a prescription from a physician (this reason is particularly important for erectile dysfunction-treating drugs).

The phosphodiesterase type 5 inhibitor (PDE5) medicines are indeed the most common products within illegal markets (mostly online, unauthorized pharmacies) [25,26]: this is explained by the high cost of the original products (Viagra, Cialis, Levitra), by the need of a doctor prescription (that can be denied in the presence of such pathologies as severe cardiac risk or previous ischemic stroke), and by patient embarrassment in talking to a physician about a particular problem. Moreover, obtaining a medicine on the Internet is often considered no different from purchasing other, regular goods. Purchasing medicines over the Internet without a prescription is illegal in Italy, as in many other countries. Nevertheless, the awareness of the health and legal risks associated with purchasing PDE5 medicines from illegal sources is often very low [27,28]. It can be estimated that approximately 6 million men in Europe might currently bypass the healthcare system to obtain PDE5 medicines [29] and the number of websites offering this type of drugs could be ranging between 4,500 and 15,000 sites [30,31]. Moreover, the production and sale of counterfeit medicines is a low-risk profitable business involving criminal organizations worldwide [32].

Thanks to the traceability system of pharmaceutical products, only medicines that are tracked throughout their entire lifecycle, from the manufacturer to the pharmacy, can circulate in the Italian legal distribution chain. As a result, in Italy the phenomenon is limited to the illegal distribution channels: gyms, discos, sex shops, ethno shops, and most of all fake pharmacies operating on the Internet, which often are run by criminal organizations [33]. In 2005 the Italian anticounterfeiting task force IMPACT Italia was instituted to monitor and survey the phenomenon of pharmaceutical counterfeiting in Italy and establish adequate countermeasures by coordinating all the Police Forces and the National Institutions involved [34].

In this article the results of a survey on PDE5 medicines seized by Italian Police Forces (Carabinieri Nuclei Antisofisticazioni e Sanità [NAS], specialized on health matters, and Guardia di Finanza [GdF], specialized on financial crimes) and Italian custom authorities or purchased from online pharmacies accessible from Italy are reported. Medicines were analyzed by the Italian official medicines control laboratory, and the results obtained were used to assess the potential health risks. The first PDE5 sample analyzed was dated 2005, but for the most part the samples were collected in the years 2008–2010.

## Aim

The aim of our study was to underline the health risks related to PDE5 medicines coming from illegal sources and illegal online pharmacies, to describe the situation in Italy as an illustrative example and to provide useful information about this problem to practitioners of general and sexual medicine in order to increase the knowledge and awareness of their patients of the risks associated with purchasing medicines from illicit distribution channels.

## Methods

Ninety-seven samples claiming to contain sildenafil, tadalafil, or vardenafil were analyzed from the beginning of 2005 to the first half of 2011. Only samples seized by Italian authorities (Carabinieri NAS, GdF, and Customs) or purchased from online pharmacies by Carabinieri NAS were considered. These last samples were part of a specific joint study between the Italian Medicines Agency (AIFA) and WHO on counterfeit medicines purchased from online pharmacies [28,33]. Internet

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