Journal of Pharmaceutical and Biomedical Analysis 87 (2014) 167–175

Contents lists available at ScienceDirect

Journal of Pharmaceutical and Biomedical Analysis

journal homepage: www.elsevier.com/locate/jpba

Review

# Understanding and fighting the medicine counterfeit market

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ARTICLE INFO

*Article history:*
Received 5 November 2012
Received in revised form 2 January 2013
Accepted 3 January 2013
Available online 11 January 2013

*Keywords:*
Medicine counterfeiting
Organized crime
Product protection
Analysis
Forensic intelligence

ABSTRACT

Medicine counterfeiting is a serious worldwide issue, involving networks of manufacture and distribution that are an integral part of industrialized organized crime. Despite the potentially devastating health repercussions involved, legal sanctions are often inappropriate or simply not applied. The difficulty in agreeing on a definition of counterfeiting, the huge profits made by the counterfeiters and the complexity of the market are the other main reasons for the extent of the phenomenon. Above all, international cooperation is needed to thwart the spread of counterfeiting. Moreover effort is urgently required on the legal, enforcement and scientific levels. Pharmaceutical companies and agencies have developed measures to protect the medicines and allow fast and reliable analysis of the suspect products. Several means, essentially based on chromatography and spectroscopy, are now at the disposal of the analysts to enable the distinction between genuine and counterfeit products. However the determination of the components and the use of analytical data for forensic purposes still constitute a challenge. The aim of this review article is therefore to point out the intricacy of medicine counterfeiting so that a better understanding can provide solutions to fight more efficiently against it.



**Contents**



## 1. Introduction

Medicine counterfeiting is a serious crime. The term needs to be clarified and harmonized but it is apparent that the problem goes far beyond a simple intellectual property quarrel. Both branded and generic medicines are indeed targeted by counterfeiters. Moreover given its life-threatening potential, the phenomenon is even more serious than the counterfeiting of other goods. Every week new instances of counterfeit medicines are discovered around the world [1] and according to the World Health Organization (WHO) [2], 10% of the world's medicines are counterfeits. Interpol refers to the "big quantities seized and sophisticated criminal networks" [3]. The seriousness of the issue is also perceived by the industrialization and globalization of the phenomenon [4–7]. Medicine counterfeiting has turned into a new branch of organized crime,

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http://dx.doi.org/10.1016/j.jpba.2013.01.009

and its links with other illegal traffics were established, together with its role in funding terrorist activities [5,8]. Efficient measures need to be implemented in order to fight these criminals. Investigations may be on the increase but dismantling of the complex and shadowy counterfeit market remains a challenge. The definition of "medicine counterfeits" should be harmonized, so that domestic and international laws can be adapted and law enforcement strengthened. This paper aims to provide a clearer understanding and overview both of the phenomenon itself and the weapons at our disposal for fighting it.

## 2. What is medicine counterfeiting?

### 2.1. Definitions and legal aspect

The definition of medicine counterfeiting, still debated, needs to be clarified [8–10]. The 1992 WHO definition has so far remained the worldwide reference, stating that "Counterfeit medicines are deliberately and fraudulently mislabeled with respect to identity or source" [2]. Some modifications have recently been proposed by the WHO, who would now rather use the term "spurious/falsely labeled/falsified/counterfeit (SFFC) medicines" [11]. Substandard medicines are another issue, since they are referred to as "out of specification products" that fail to meet quality specifications and are manufactured by legitimate firms [9,12]. In the definition of SFFC medicines, the WHO insists on the public health meaning and the life-threatening aspect of counterfeiting.

Counterfeiting can on the other hand be legally referred to as a violation of intellectual property (IP) detained by owners of copyrights, patents, trademarks. Recently defined in the Agreement On Trade-Related Aspects Of Intellectual Property Rights (TRIPS), "counterfeit trademark goods" shall mean "any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation" [13]. IP infringements are punishable by law. The advantage of this approach is consequently that it allows the companies with branded medicines to partially defend themselves. However punishments do not really fit the crime, since they do not take the public health problem into consideration. Moreover generics manufacturers cannot use this strategy [7,9,10].

The countries fail to agree on a definition of medicine counterfeiting. The legislation consequently differs between them, making overview difficult. The major problem is indeed the lack of an international legal framework [10]. According to the Anti-Counterfeiting and Trade Agreement proposed by several countries, counterfeiting cases on a commercial scale should attract criminal procedures and penalties [14]. Swiss trademark-holders have for instance three means at their disposal: civil law, criminal law, and the customs [15–19]. Most countries already have laws for pursuing IP infringers but few focus on medicines and on the public health issue this raises. In some regions court decisions and judicial processes are frequently delayed. Countries and cases show a huge disparity [4]. Internet pharmacies pose particular problems in that the relevant legislation is often nonexistent [8]. For these reasons the "public health" meaning of counterfeiting should probably be dissociated from the IP infringing one and the legislation mainly focus on the first [9,10]. "Counterfeit medicines" will be the expression used in the next paragraphs, following the definition of the WHO [2,11].

### 2.2. Types of counterfeits and targeted medicines

Medicine counterfeits can differ in type and quality, mostly depending on their destination (Table 1).

Copies increasingly contain the same active pharmaceutical ingredients (APIs) as the genuine products, sometimes even in the same proportion [20]. Other counterfeits contain no APIs, the wrong amount of APIs, or even other APIs. Wrong APIs are randomly selected or chosen with a chemical structure similar to the genuine ones [21]. They can provoke adverse events and mask the clinical signs that would enable appropriate care [22]. Other products contain a wrong API that makes the patient think they are curing the disease but are not, e.g. the counterfeits that reduce the fever caused by malaria but fail to cure the disease itself [23]. A further variant is drug diversion in which expired genuine medicines are repacked, making their identification particularly difficult [24]. Reused components or containers may be recycled to constitute hybrid counterfeits [25]. The medicines themselves are not the only items to be counterfeited. The packaging, APIs and documentation are also often targeted [25,26].

**Table 1**
Different types of counterfeits found on the market.

| Counterfeit | Types of counterfeit | Characteristics |
|---|---|---|
| Medicines | No API | Brand medicines for industrialized areas |
| | Wrong API | Generics for developing countries |
| | Right API, wrong dosage | |
| | Very good copy | Lifestyle medicines for industrialized countries |
| | | Sold via internet |
| | Expired genuine medicines | Repackaged with fake dates |
| | Hybrid counterfeits | Containing reused components |
| APIs | An unauthorized API sold as an authorized API | |
| | API manufactured by another process | |
| | API produced by unregistered firms and fraudulently mislabeled | |
| Medical devices | Old repackaged material | |
| | Inferior-quality material fraudulently mislabeled | |
| Packaging | Copy of the genuine packaging | Updated fake data Items sometimes nonexistent |
| Documentation | False documentation (Certificate of Suitability, import status, etc.) | |

*Source*: European Alliance for Access to Safe Medicines (EAASM) [25], Seiter [20], Primo-Carpenter et al. [4], Vanderdonck et al. [26], International Medical Products Anti-Counterfeiting Taskforce (IMPACT) [2], Newton et al. [6,21], Berman et al. [45], Harris et al. [23], Fernandez et al. [22], Mukhopadhyay [24], Nigerian Food and Drug Administration (NAFDAC) [55].