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Forensic intelligence for medicine anti-counterfeiting

Klara Dégardin [a,*], Yves Roggo [a], Pierre Margot [b]

[a] F Hoffmann-La Roche Ltd, Bldg 250 Room 3.504, Wurmisweg, 4303 Kaiseraugst, Switzerland
[b] Institute of Forensic Science, School of criminal Sciences, University of Lausanne, Batochimie, 1015 Lausanne, Switzerland

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ABSTRACT

Medicine counterfeiting is a crime that has increased in recent years and now involves the whole world. Health and economic repercussions have led pharmaceutical industries and agencies to develop many measures to protect genuine medicines and differentiate them from counterfeits. Detecting counterfeit is chemically relatively simple for the specialists, but much more information can be gained from the analyses in a forensic intelligence perspective. Analytical data can feed criminal investigation and law enforcement by detecting and understanding the criminal phenomenon. Profiling seizures using chemical and packaging data constitutes a strong way to detect organised production and industrialised forms of criminality, and is the focus of this paper. Thirty-three seizures of a commonly counterfeited type of capsule have been studied. The results of the packaging and chemical analyses were gathered within an organised database. Strong linkage was found between the seizures at the different production steps, indicating the presence of a main counterfeit network dominating the market. The interpretation of the links with circumstantial data provided information about the production and the distribution of counterfeits coming from this network. This forensic intelligence perspective has the potential to be generalised to other types of products. This may be the only reliable approach to help the understanding of the organised crime phenomenon behind counterfeiting and to enable efficient strategic and operational decision making in an attempt to dismantle counterfeit network.

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1. Introduction

Ten per cent of the world's medicines are counterfeits according to the World Health Organization [1]. New cases are detected every week [2]. The manufacturing and process conditions are a direct threat to patients' health [3,4]. Indeed several kinds are devoid of any Active Pharmaceutical Ingredient (API) or are even stuffed with toxic compounds [1,5]. Society at large is also economically threatened [3,6,7]. There are several reasons for the development of the phenomenon, like the difficulty in agreeing on a definition of medicine counterfeiting and huge deficiencies in legislation and enforcement [3,8–11]. Furthermore counterfeiting is financially rewarding and largely risk-free [1]. According to some sources [6,12–14], terrorist groups finance their activities through the counterfeit trade and major crime syndicates are involved as well. Rapid communications like the internet have also boosted links between criminal networks [12]. Understanding and dismantling this complex and shadowy market remains a challenge because counterfeiting has become a structured trade with manufacturers, wholesalers, distributors and local sellers [6,15]. The support given by the different anti-counterfeiting institutions is also slow and local or regional. The response needs to take its cue from the threat it is facing: it needs to be rapid, reactive, and globalised [16,17]. Manufacturers are increasingly introducing techniques for protecting their products, like coding and marking of the packaging or medicine itself [18–22].

Analytical services are mostly working in the perspective of quality control and have been used occasionally either to determine a danger from counterfeits or to demonstrate that a product is not genuine. Collating and organising analytical data in a systematic fashion was always considered an expensive and difficult to handle process and therefore remained a chemistry problem rather than a forensic science problem. It was the initial perception that these data may offer much more value that led to the investigation that is described herein. This is well in line with recent publications offering a generic approach to forensic intelligence [23].

It was rapidly evident that analytical data provided by the chemical and packaging study could combine to provide forensic intelligence and give an insight into the phenomenon at three different levels [17].

* Corresponding author. Tel.: +41 61 6888601.
E-mail addresses: klara.degardin@roche.com (K. Dégardin), yves.roggo@roche.com (Y. Roggo), pierre.margot@unil.ch (P. Margot).

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First, quick detection methods can be developed and deployed, in order to speed up the handling of counterfeit cases on a local basis. While fast and efficient analysis of counterfeit protein medicines is still a research area [24], many papers have been published about the identification of counterfeit Tablets and capsules [25]. Differentiating between counterfeit and genuine products is now rarely an issue given the multiplicity of analytical tools that have proven effective, like chromatography and spectroscopy [26–28] implemented in either the laboratory or in the field [29,30].

Second, if a counterfeit case is discovered, its chemical composition has to be determined so that the danger for the patients is evaluated. Again several analytical methods have been developed for this purpose, like vibrational spectroscopy, imaging and mass spectrometry [31–34].

The third step of counterfeit analysis constitutes the focus of this paper. It is the logical and structured use of analytical data to provide a forensic intelligence insight into this criminal phenomenon and an intelligence-led capacity to fight it. Counterfeit medicine profiling is still in its infancy [35–37], with forensic analyses remaining essentially a research interest. Results from the illicit drugs field [38] suggest that it could provide highly valuable information on counterfeit networks to investigative agencies.

Intelligence is the process enabling the comprehension of a criminal phenomenon (Fig. 1) [39]. It first requires the acquisition of meaningful data by several analytical means. Relevant information, for instance from chemical and packaging analyses, is then integrated and organised into a structured database, in the form of a memory. The memory is permanently revised, in an iterative way, fed by new information. The subsequent analyses of the memory give an updated perceived view of the on-going phenomenon under scrutiny and allow taking strategic and operational decisions, to inform and influence the decision-makers. The objective is finally to enable the interpretation of the crime and its reconstruction.

The objective of the study was to test the hypothesis that studied counterfeits of a commonly counterfeited type of capsules come from a criminal organisation producing at an industrial scale. For this purpose the potential of chemical and packaging profiling and the associated intelligence has been evaluated.

A database, or structured memory, has been initialised. In this way, the application of the process should allow the fast analysis of each new case and its linkage with former counterfeits. A better understanding of the market and the studied networks has derived from the study, as well as a reconstruction of the crime. Another impact of such a new approach is that it suggested priorities of intervention, orientation of investigations and preventive measures against the phenomenon.

Counterfeits were seized almost independently from one another, around the world, through different channels of distribution. They were known to be counterfeits since they were relatively easily detected. The unknown resided in how the counterfeits came where they were seized. Until the networks producing and distributing these counterfeits are dismantled, these facts will remain unknown except if strong indicators can be retrieved to infer on the situation.

There can be a number of propositions or hypotheses. The first one is that an industrialised criminal organisation is behind the counterfeiting of the studied product, the hypothesis being that there is a single producer, somewhere with industrial capacity and access to chemicals. The alternate hypothesis is that there are multiple producers, each close to where the seizures were made.

The allegation that the phenomenon is part of global organised criminality tends to favour one producer, but possibly several sites, with access to raw products, which may control the whole distribution chain or may have a network of distributors, or wholesalers, some of which may receive the counterfeit product, but may independently organise, at a local level, packaging and conditioning.

In any of these situations there are a number of observations that could support and help differentiate the various propositions.

Great uniformity in products or great uniformity within batches of products can be supposed, but with a diversity depending on the availability of raw materials, their cost and convenience. In the hypothesis of a unique producer, the analogy can be made with Roche products. For Roche products a narrow variability within a product type can be demonstrated, whether produced on one site or on two different sites so that it stays within quality control admissible ranges. A low intra-variability within each site should be observed as well as a low intra-variability within Roche product.

If a same producer is considered but with variable productions, the consistency should be reduced, and the variability observed can be low but result in various consequences. The same API could e.g. be detected among the counterfeits or different APIs while the same excipients would be used.

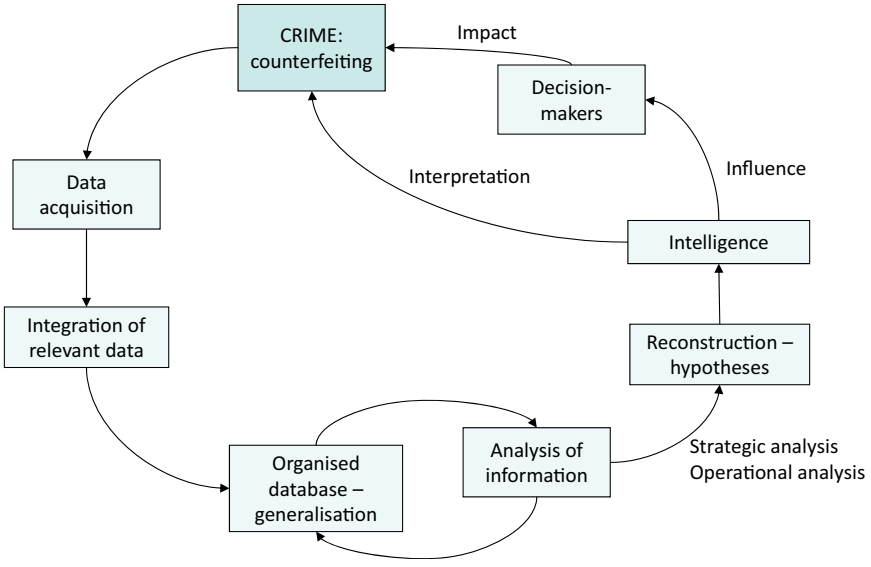

Fig. 1. Main steps of the iterative process of intelligence applied to the analysis of counterfeits (adapted from Ribaux and Margot [39]).

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