

Risk reduction measures for counterfeit medicines in the supply chain

Ana Grozdanoska Zdravevski*, Nikola Simonovski, Nada Popstefanova

ALKALOID AD Skopje, Blvd. A.Makedonski 12, 1000 Skopje, N.Macedonia

Introduction

The health consequences of counterfeit medicine might be severe since the product may contain improper amounts or harmful ingredients.

Given the impossibility of obtaining complete protection against counterfeit medicines, it is frequently necessary to respond appropriately when one is discovered. This covers more extensive preventative actions in addition to the mandatory notification of supervisory or investigative authorities. Considering that the phenomena of counterfeit medicines are very dynamic and flexible rather than static, it calls for continuing adaptation or further development of defense systems into the pharmaceutical world (Cohn et al., 2012).

Materials and methods

This short paper presents literature data, which is analyzed and presented in a way of minimization of risk of counterfeit medicines in the supply chain.

Results and discussion

Counterfeit-proof features, tamper-evident closures, and unique encoding with package-specific serial numbers can help to prevent against counterfeit medicines on the market. Coding and serialization ensure high level of transparency in the market. Finally, there are countless additional applications for these codes. Potential uses include, for example, electronic distribution of the package information leaflet or as part of the pharmacovigilance procedure. Fighting against counterfeit medicines in the company comprises four essential aspects: monitoring, knowledge building, prevention and reaction. In terms of

monitoring, a globally standardized database has proven to be a suitable tool for recording the global occurrence of counterfeit medicines and for establishing appropriate processes for case processing and notification of the authorities on this basis.

According to the so-called EU Falsified Medicines Directive 2011/62/EU, which is integrated in the EU GMP Directive 2001/83/EC, at least two safety features must be fulfilled for the EU:

- encoding with a unique identifier in the form of a two-dimensional code combining a unique product identification number with a randomized serial number (2D data matrix code)
- the application of an anti-tampering device → tamper-evident closures.

This data serves for internal reporting and the implementation of anti-counterfeiting measures for manufacturers and marketing authorization holders in particular. At the same time, the data serves as the foundation for assuring counterfeit drug alerts in compliance with national rules (Werner, 2020).

Given the global dimension of this criminal activity, surveillance by market participants should be organized centrally in a unified global system. Despite the global nature of counterfeit medicines, there is currently no requirement to notify across national borders, nor is there any close cooperation in place among the authorities responsible for the various aspects that can be considered firmly established in all cases. These authorities include customs officials, criminal investigation and prosecution authorities, and medical product regulatory authorities. Samples may be used as evidence in legal proceedings. Preventive measures are focus on two main aspects:

- Education about counterfeit medicines and how those potentially affected can protect themselves.

- Safety features that make counterfeits easier to recognize, that reveal tampering and/or that are difficult to copy

Processes therefore must be in place and include legally mandated notice requirements. Established escalation mechanisms and committees can usually be used for this purpose. If widespread counterfeit medicine is discovered, the media and public will undoubtedly be interested, and it is therefore vital to be well prepared to deal with such a scenario effectively. Preventive crisis communication strategies are quite useful in this situation (Schwarze, 2022).

Table 1. IFPMA'S 10 principles on counterfeit medicines

Principle	Description
WHO global coordination is necessary	As the leader on global health matters, and particularly with respect to threats to public health in developing countries, the WHO has a key role to play. Strong coordination among international organizations is needed to ensure that all aspects of this problem are adequately addressed.
Counterfeiting is a crime!	By deliberately and deceitfully attempting to pass themselves off as something that they are not, namely genuine approved medicines, counterfeit medicines pose a global public health risk that can lead to resistance to treatment, illness, disability and even death.
Counterfeiters do not discriminate between medicines	They can be falsified versions of patented medicines, generic medicines or over-the-counter medicines and exist in all therapeutic areas. They range from medicines with no active ingredients to those with dangerous adulterations.
Atents have nothing to do with fake medicines	Purely commercial patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the production of counterfeit versions of genuine approved medicines.
Counterfeit and substandard medicines are not the same	A medicine which is approved and legally manufactured but does not meet all quality criteria is substandard, and may pose a significant health risk but should not be regarded as counterfeit.
Fake and illegal medicines are not the same	A medicine that is authorized for marketing by one regulatory authority but not by another should not be regarded as counterfeit on these grounds alone in the latter's territory.
Empower regulators	The problem is more prevalent in countries where regulatory oversight and enforcement are weak.
Counterfeit medicines	Countries should adopt measures that will stop trade in medicines that do not contain

trade must be stopped
Counterfeit medicines are everybody's business

Global cooperation is needed

the ingredients that they purport to contain.

Public and private organizations; national regulatory and enforcement agencies; health professionals; patients; research-based and generic pharmaceutical manufacturers; drug distributors, wholesalers and retailers play a role in preventing counterfeits.

Counterfeiting does not recognize borders, new mechanisms that bring together the expertise of medicines regulatory agencies, enforcement agencies, healthcare providers and the private sector should be supported.

Conclusion

Rapid involvement of responsible bodies such as the WHO and country drug regulatory was needed to facilitate investigation and removal of the counterfeit medicines. To ensure that other suppliers do not have the drugs or batches in concern, procurement bodies, implementers, and stakeholders require prompt notification of the counterfeit medicines.

In efforts to decrease risk of counterfeit medicines, the goal is to ensure an adequate and affordable supply of quality medications to the patients.

References

- Cohn, J., von Schoen-Angerer, T., Jambert, E., Arreghini, G., Childs, M., 2013. When falsified medicines enter the supply chain: description of an incident in Kenya and lessons learned for rapid response. *Journal of Public Health Policy*, 34, 22-30. doi:10.1057/jphp.2012.53.
- Werner V., 2020. 13.B.10 Measures for the protection from counterfeit medicinal products during packaging. *GMP Compliance Adviser*. GMP-Verlag Peither AG. Available at: https://gmpcadviser.gmp-verlag.de/?action=infounit&value=E1azhFWWtC&anchorlink=Practice_13_Verpackung_13B_023_xml&uilang=de-DE, (Accessed: 26.05.2023).
- Schwarze S., 2022. 21.H Fight against counterfeit medicines. *GMP Advisor*. GMP Compliance Adviser. GMP-Verlag Peither AG. Available at: https://gmpcadviser.gmp-verlag.de/?action=infounit&value=peihnbVaIv&anchorlink=Information_Information_00_Preface_ID0EKCB1_177_xml&uilang=de-DE, (Accessed: 26.05.2023).
- Kleissendorf R., 2019. 13.A.6 Protection against counterfeit medicinal products. *GMP Compliance Adviser*. GMP-Verlag Peither AG. Available at: URL https://gmpcadviser.gmp-verlag.de/?action=infounit&value=mZfMcD0245&anchorlink=Information_Information_00_Preface_ID0EQZAE_087_xml&uilang=de-DE, (Accessed: 26.05.2023).