

ANALYTICAL STRATEGIES FOR THE DETECTION AND CHARACTERIZATION OF COUNTERFEIT MEDICINES

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Drug counterfeiting has increased dramatically over the past decade around the world and poses a serious threat to human health, particularly in developing countries. Its definition needs to be clarified and harmonized since in relation to medicines the problem is not limited to a violation of intellectual property rights but clearly involves all kinds of poor quality pharmaceutical products, including falsified and substandard drugs. It is generally considered that counterfeit medicines represent at least 7 % of the worldwide pharmaceutical market but it is also well known that this proportion is much higher in many African, Southeast Asian and Latin American countries where drugs used for the treatment of life-threatening diseases such as malaria, tuberculosis and AIDS have been particularly targeted by counterfeiters. A wide panoply of techniques have been used to detect counterfeit drugs, ranging from simple and cheap methods suitable for field analysis, such as colorimetric tests and thin-layer chromatography, to more sophisticated analytical tools, such as mass spectrometry (MS) and NMR spectroscopy. In fact the selection of the most appropriate techniques will depend on different factors, such as where the analyses is to be performed, the kind of information to be obtained (only on active ingredients or on all components of the pharmaceutical formulation, qualitative or quantitative analysis), the training and expertise of the operators, the cost and the speed of the analyses, etc. The most commonly used analytical tools for the screening of counterfeit medicines belong to two main groups: spectroscopic and separation techniques. Among the spectroscopic methods, vibrational spectroscopic techniques are often employed: mid-infrared (FTIR), near-infrared (NIR) and Raman spectroscopies. Most of these techniques share some interesting features: they are fast, non-destructive, require no or minimum sample preparation and dry formulations can be sometimes investigated through the packaging material. Chemometric tools are usually needed to extract significant information from the spectra as well as to discriminate and classify the counterfeit samples. Among the separation techniques, liquid chromatography (LC), including ultra high pressure LC (UHPLC), coupled to UV or MS detection, is by far the most popular tool for the identification and quantification of active ingredients in counterfeit drugs and for impurity profiling. Capillary electrophoresis (CE) is also increasingly used for these purposes and might be a particularly interesting alternative for the analysis of counterfeit biopharmaceuticals. Examples of generic approaches developed for the detection of counterfeit erectile dysfunction and antimalarial medicines will be presented [1-3]. These two classes of drugs are probably the most counterfeited ones in Europe and in sub-Saharan Africa, respectively.

References

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