Forensic Analysis and Classification/Sourcing of Counterfeit Pharmaceutical Products

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The World Health Organisation (WHO) defines counterfeit drugs as medicines which are manufactured below established standards of safety, quality, and efficacy and are deliberately and fraudulently mislabeled to hide their identity and source. They may include products with the correct ingredients or with the wrong ingredients, incorrect quantities of the active pharmaceutical ingredients (API), as well as fake packaging. Counterfeiters are employing increasingly innovative, sophisticated and specialised manufacturing techniques, which makes detection more challenging.

Forensic examinations using various advanced analytical techniques are necessary to provide conclusive results in the detection and characterisation of counterfeit drugs. The techniques used include qualitative and quantitative analyses of the drugs and excipients such as Raman spectroscopy, Fourier Transform Infra-red (FTIR) spectroscopy, Scanning Electron Microscopy with Energy Dispersive X-ray detector (SEM/EDX) and Liquid Chromatography. Techniques of questioned document examination were used in the analysis of the packaging materials of suspected pharmaceutical products. Isotope Ratio Mass Spectrometry (IRMS) is also applied to discriminate between fake and authentic drugs.

As the molecular spectroscopic methods like Raman and FTIR, provide fingerprint data on the suspected pharmaceutical products, information from these analyses can associate different counterfeit samples and provide linkages back to their sources. Additionally, the IRMS is also used to provide information in the classification and sourcing of these fake drugs.

Findings and conclusions drawn from data obtained with the application of all the various techniques to erectile-dysfunction drug samples such as Cialis will be presented.