IMPLEMENTATION OF GENERIC ANALYTICAL METHODS TO FIGHT AGAINST COUNTERFEIT MEDICINES

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Counterfeit of medicines are highly problematic throughout developing countries because of the direct threat they pose to the lives of patients and their contribution to the development of drug-resistant strains in particular for killing diseases such as malaria, infections, etc… A picture of results published from a large scale study carried out by USP-USAID-WHO was challenging [1] : one third of antimalarial medicines sampled in three African nations were found to be substandard or counterfeit. Another study reported unimaginable proportions rising up to 80 % of counterfeit. Besides the public health consequences, such medicines have also economical consequences and negative reputation on the pharmaceutical industries. However, health authorities at national, regional and international levels are still trying to fight against this scourge by implementing several strategies that needs to be reinforced through adequate analytical methods for quality control. It is important that these analytical methods being generic, affordable financially, fast and having specific detection. In this context, a strategy focused on two axes is presented: At first, generic analytical methods were developed by means of experimental design combined with *Design Space* optimisation strategy [2] in order to allow detecting and tracing simultaneously several substances belonging to a pharmacological group along with substances of interest (conservatives, impurities, etc…). Liquid Chromatography (LC) and Capillary Electrophoresis (CE) techniques were considered to develop the analytical methods. 16 antimalarial medicines were able to be monitored in presence of 4 conservatives using LC and CE, respectively, 20 non-steroidal anti-inflammatory (NSAID) medicines in presence of the 7 molecules of interest using LC. These methods were used as reference in the second axe strategy that consisted to the transfer of the developed generic methods towards others while maintaining as much as possible practical objective regarding the effectiveness of decision making by legal authorities. The first consideration was the use of a CE device equipped with a detection system based on Light-Emitting Diodes developed to allow a significant reduction in the costs of the CE equipment [3] while still using very small volume of solvents. The new device was applied for antimalarial medicines quantification. Another transfer concerned paracetamol in syrup by near infrared spectroscopy (NIR). For that purpose, chemometric tools were applied to extract the significant information [4] and to allow detection and quantification of several dose of this NSAID. NIR does not use any solvent at all or very little. Very interesting and promising results were obtained.

References

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