

# CONTRIBUTION TO FIGHT AGAINST COUNTERFEIT MEDICINES APPLYING SEVERAL ANALYTICAL TOOLS

**R.D. MARINI<sup>1</sup>, J. MBINZE KINDENGE<sup>2</sup>, M.L.A. MONTES<sup>3</sup>, B. DEBRUS<sup>1</sup>, P. LEBRUN<sup>1</sup>, J. MANTANUS<sup>1</sup>, E. ZIEMONS<sup>1</sup>, S. RUDAZ<sup>3</sup>, Ph. HUBERT<sup>1</sup>**

<sup>1</sup> *Laboratoire de Chimie Analytique, Département de Pharmacie, Centre Interfacultaire de Recherche du Médicament (CIRM), Université de Liège, B36, Avenue de l'Hôpital 1, B-4000 Liège, Belgium.*

<sup>2</sup> *Laboratoire d'Analyse et de Contrôle des Médicaments et Denrées Alimentaires (LACOMEDA), Faculté des Sciences Pharmaceutiques, Université de Kinshasa, BP 212 Kinshasa XI, République Démocratique du Congo.*

<sup>3</sup> *School of Pharmaceutical Sciences – EPGL, University of Geneva, University of Lausanne, Bd. d'Yvoy 20, 1211 Geneva 4 – Switzerland.*

Counterfeiting has been dramatically increasing this last decade throughout the world and particularly in developing countries [1], where unimaginable proportions rising up to 80 % of counterfeit have been reported, meaning that a patient has only 1 chance over 5 to have a medicine that can really be useful and helpful. This negative situation presents many consequences such as adverse impacts on public health, economics and negative reputation for the pharmaceutical industry. Recognizing the impact of this situation, health authorities at national, regional and international levels are trying to fight against this scourge. For example, several strategies are discussed among which the setting-up of effective quality control that need to be reinforced through generic, fast and specific detection methods. In order to overcome the issue of counterfeiting, several analytical tools were applied to the detection and quantitation of counterfeit drugs: liquid chromatography (LC), capillary electrophoresis (CE) and near infrared spectroscopy (NIR). For LC, a generic method was developed for monitoring 16 antimalarial drugs in presence of 4 conservatives applying a design space optimisation strategy [2]. The developed generic method was applied to confirm the presence of artesunate and amodiaquine in a pharmaceutical dosage form (tablet). By means of a short method, the assay of these two active ingredients was carried out and their content was found to be conform. Concerning CE, a device equipped with a detection system based on Light-Emitting Diodes has been developed and allowed for a significant reduction in the costs of the CE equipment, thus in the analysis of active ingredients [3]. The new device was tested to monitor and quantify anti-HIV drugs with Micro Emulsion Electro Kinetic Chromatography technique. For NIR, chemometric tools were needed to extract the significant information [4], thus allowed the detection of counterfeit low-dose pharmaceutical syrup of paracetamol regarding the concentration of the analyte and the composition of the syrup. Very interesting and promising results were obtained with these tools in several pharmaceutical dosage forms, thus strengthening their application in the fight against counterfeiting.

## References

- [1] World Health Organisation (WHO), Counterfeit medicines, Fact Sheet no. 275 (2010), <http://www.who.int/mediacentre/factsheets/fs275/en/print.html> , Accessed 387 January 27, 2010.
- [2] P. Lebrun et al., *Chemom. Intell. Lab Sys.*, 91, pp. 4-16 (2008). <http://orbi.ulg.ac.be/handle/2268/1640>
- [3] R. D. Marini et al., *Reliable low cost capillary electrophoresis device for drug quality control and counterfeit medicines*, *J. Pharm. Biomed. Anal.*, Submitted (2010). <http://orbi.ulg.ac.be/submit?resume=137526>
- [4] E. Ziemons et al., *Acetaminophen determination in low-dose pharmaceutical syrup by NIR spectroscopy*; *J. Pharm. Biomed. Anal.*, In press. <http://hdl.handle.net/2268/60504>

---

Thanks to the Belgian Coopération Universitaire au Développement, the European Education Project (EU-ACP-Edulink DEV-AQM), the Walloon Project PPP (Convention OPTIMAL DS N°917007) and the University of applied sciences of western Switzerland (Fribourg) (Projet d'institut iTIN, Sagex n°11480/19870).