The project in a nutshell

- Low-cost analytical device based on capillary electrophoresis for counterfeits detection and sub-standard drug quality control
- Scientific and technical support with theoretical and practical training in emerging countries

Context

The proportion of counterfeit medicines has dramatically increased in the last few years. According to numerous official sources, the proportion has reached 80% in African countries. The fight against this calamity is complex and different levels of action are necessary. Among them, the quality control of batches imported into the different countries can be achieved, although this strategy is often difficult to apply due to a lack of suitable analytical equipment in developing countries. Simple, reliable, and cost-efficient drug control approaches are needed and the currently used methods entail numerous drawbacks such as (i) the availability of reference substances, (ii) the maintenance of analytical instruments, and (iii) the availability and costs of consumables.

In this context, the use of capillary electrophoresis (CE) appears of utmost interest since the separation is achieved in a capillary of reduced dimension (total volume of 1 μL), filled with an aqueous buffered solution of electrolytes. No organic solvent is needed and injection volumes are in the nanoliter range, which is perfectly adapted to the low availability of reference substances. Another CE feature is the equipment simplicity, with no mechanical constraint and simplified maintenance, only requiring a periodical control of the electrodes and detection performance during routine analyses. CE is now recognized by numerous Pharmacopeia and can therefore be used as a validated analytical procedure according to international guideline recommendations.
Prototype

The University of Geneva (Switzerland) collaborated with the University of Applied Sciences of Fribourg (Western Switzerland) and the Geneva Pharmacy Hospitals (Switzerland) to build a low-cost CE device and help transitional countries to fight against counterfeit medicines.

A first CE prototype was built during a 2-years period, in which the mechanical and electronic aspects were assessed, leading to an original detection device based on a diode technology.

After β-testing in several laboratories, some modifications were included to improve the system robustness, leading to a second prototype. Thanks to the financial support of sponsors and the creation of a non-profit organization (Pharmelp), eight final prototypes were built leading to several missions in emerging countries.

Method

In order to analyze a high number of compounds and benefit from the device with basic chemistry knowledge, simple and generic methods were developed and validated. A strategy based on multiple injections is currently applied for the simultaneous qualitative and quantitative analysis of more than 80 drugs from the list of the 200 essential medicines defined by the World Health Organisation.
Missions

The training of laboratory operators was the main core of all missions so they could (i) use the device, (ii) implement the methods, and (iii) perform the quality control of drug material (active principal ingredient) and drug products (pharmaceutical formulations) according to the regulatory guidelines. Getting feedback regarding the instrument, the methods, and the field constraints was also part of the missions.

The first mission took place at the “Laboratoire National de la Santé” in Bamako (Mali) in 2009.

The second mission was achieved in 2011 at the “National Health Product Quality Control Centre” in Phnom Penh (Cambodia).

In 2012, a mission involved the “Laboratory of Analytical Chemistry” of the “Bromatology, Medicine and Pharmacy Department” at the University of Cheikh Anta Diop in Dakar (Senegal), in close collaboration with the “National Health Laboratory of Senegal”. A PhD thesis was achieved in collaboration with the University of Geneva.

In 2013, a mission was initiated with the University of Kinshasa (Republic of Congo), involving collaboration with the University of Liege (Belgium).

Two other projects are currently planned and will be implemented in 2015, with one prototype in Rwanda and one in Burkina Faso.

Convention

The last prototypes are involved in missions based on a convention signed between Pharmelp, the University of Geneva, and another non-profit organization, Pharmaciens sans Frontières (PSF). Drug products found in the areas covered by PSF are analyzed either locally by a low-cost CE provided by Pharmelp or by the University of Geneva from drugs collected and shipped by PSF. A first project was implemented in Tanzania at the Lugala Hospital in 2012 and another one was initiated in Madagascar with the University of Antananarivo in 2014.
Conclusion

A low-cost CE was successfully built and implemented in emerging countries. Due to its short analysis time, simple instrumentation, low sample and solvent consumption as well as reduced operating costs, this device is perfectly adapted to (i) rapidly evaluate the quality of drugs, (ii) establish the presence of the active principle(s), (iii) quantify the amount of the active principle(s), and (iv) give evidence regarding the presence of degradation impurities. CE can thus be considered an appropriate tool to tackle the counterfeits problems.

Perspectives

In addition to continuous improvements of the methodological and technical aspects of the low-cost instrument, an educational program will be developed in the next few years related to the continuous education of scientists using CE in emerging countries.

The main objective is to increase the knowledge and the practical handling of the technique using e-learning tools. The program is based on three main sub-projects:

(i) development and implementation of an e-learning module related to the theoretical concepts of CE

(ii) development and implementation of a hybrid course based on practical work and computer–assisted simulations

(iii) participation to a research project, PracTICE (collaboration and tutoring supports for computer-supported collaborative practical learning)

Stakeholders

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Samuel Roth (University of Applied sciences of Fribourg)

Prof. Claude Rohrbasser (Pharmelp)

Prof. Pascal Bonnabry (Geneva Pharmacy Hospitals)

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