CAPILLARY ELECTROPHORESIS FOR THE DETECTION OF SUBSTANDARD AND FALSIFIED MEDICINES: 5-YEARS EXPERIENCE IN SENEGAL

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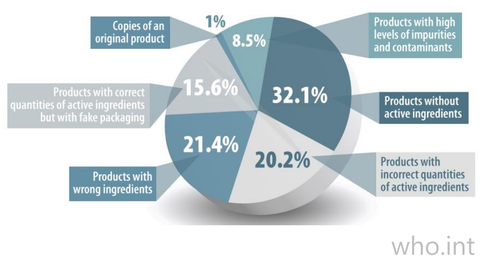
The situation

Substandard and falsified medicines may cause harm to patients and fail to treat the diseases for which they were intended. They lead to the loss in confidence in medicines, healthcare institutions, and health systems.

Identifying a substandard or falsified medical products is very difficult and different levels of action are needed to control their suitability and conformity.

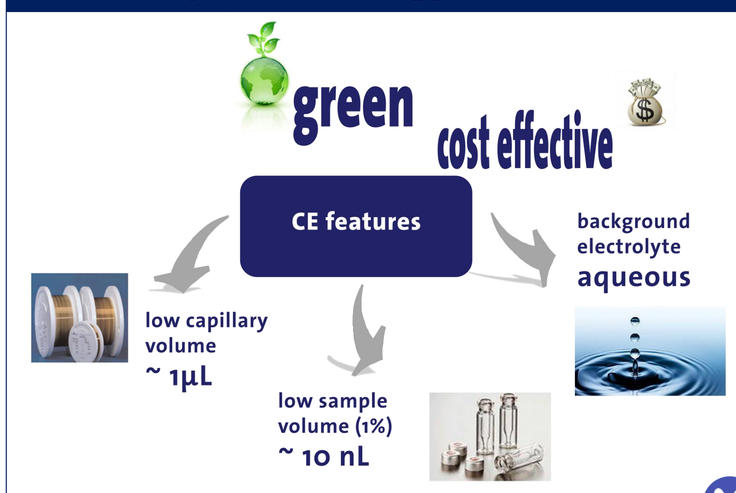
Among them, the **quality control** of batches imported into the different countries can be achieved, although this strategy is often difficult to apply due to:

- the lack of suitable analytical equipment
- the high cost of instruments, maintenance, and consumables
- the low availability of reference substances and consumables



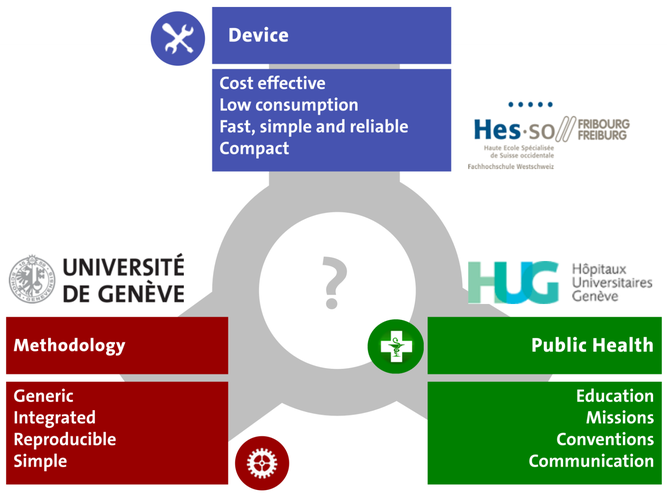
Simple, reliable, and cost-efficient drug control approaches are thus needed.

The analytical strategy



The use of **capillary electrophoresis (CE)** is particularly appropriate for cost-effective drug control since no organic solvent is needed and injection volumes are in the nanoliter range, which is perfectly adapted to the low availability of reference substances.

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



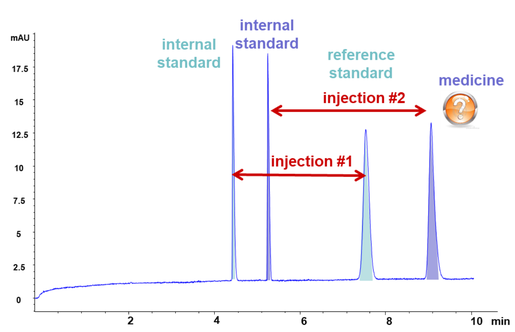
The implementation in Senegal

To enable the analysis of various pharmaceuticals, simple and generic methods were developed at UniGE in **Switzerland**, based on **multiple injections** to enable the **simultaneous** characterization (ID) and quantitation (dosage) of drugs.

The methods were successfully validated according to ICH guidelines.

They were transferred in **2012** to the University of Cheikh Anta Diop of Dakar (UCAD) in **Senegal** together with the low-cost device, and the laboratory staff was trained to:

- use the instrument
- implement the methods
- perform the quality control of drug products



ID | corrected migration time ratio

Dosage | corrected area ratio

Training on ECB in 2012

Demo on WynCE in 2016

New methods were also developed at UCAD to analyze specific medicines from the **WHO list of essential medicines** that are available in Senegal, as well as in other emerging countries (from Africa and elsewhere).

A second apparatus was installed in **2016**.

The results

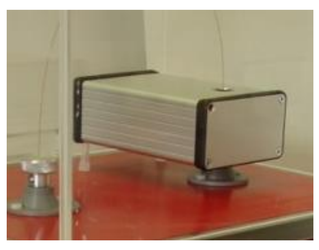
Over the last 5 years, more than **200 samples** of manufactured medicines were collected and eventually controlled with the low-cost CE device. The analyses revealed:

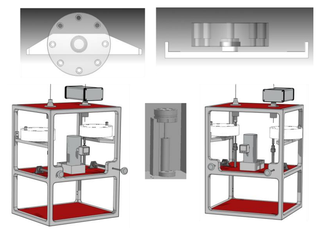
- **overdosing**: for 17% of quinine samples and for 64% of phenobarbital samples
- **underdosing**: for 25% of captopril samples
- **compliance**: for trimethoprim-sulfamethoxazole combinations, amoxicillin, metronidazole, diclofenac, and paracetamol samples

API	CE method
Quinine Metronidazole	BGE: phosphate buffer pH 2.5 IS: procaine Analysis time: 10 min
Paracetamol Trimethoprim-sulfamethoxazole	BGE: phosphate buffer pH 6.1 IS: furosemide Analysis time: 5 min
Phenobarbital Captopril Amoxicillin Diclofenac	BGE: borate buffer pH 9.0 IS: benzoic acid Analysis time: 3 min

Results of QC analyses were published and sent to the medical authorities of Senegal. The methods were then transferred and applied at the **national control laboratory for drugs**.

The device





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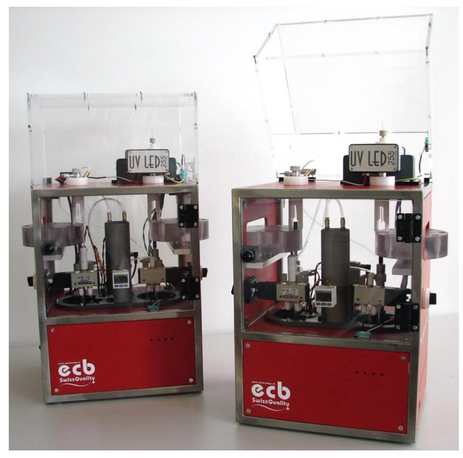
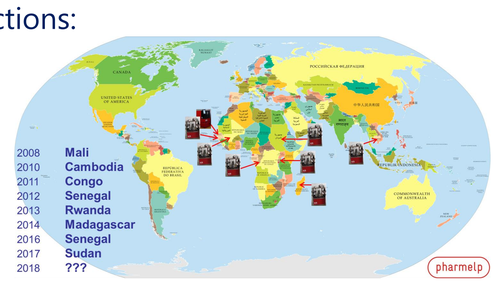


The features and perspectives

The low-cost CE device combined with validated methods demonstrated good quantitative performance, bringing a **reliable support for the QC** of medicines in Senegal. It also allowed **sustaining education and competence transfer** between UniGE and national institutions in Senegal.

The project shall be further extended in several directions:

- bring the technology and the knowledge to other **emerging countries**



- apply the strategy to **traditional medicines**

- develop a **new-generation prototype**
  - ✓ greener
  - ✓ more autonomous
  - ✓ more affordable
  - ✓ open-source
  - ✓ user-assisted

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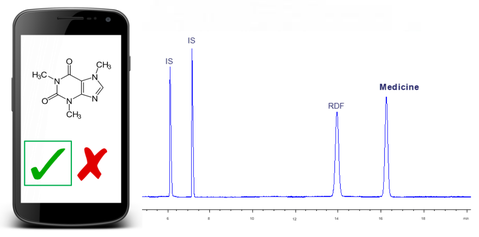

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