

Access, Quality and Pricing: Innovation Challenges in Low and Middle Income Countries

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April 30th, 2019

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A A

By **BENOÎT FAUCON** in Luanda, Angola, **COLUM MURPHY** in Guangzhou, China, and **JEANNE WHALEN** in London

When customs officials in Luanda, Angola, searched a cargo container from China, they found something hidden inside a shipment of loudspeakers: 1.4 million packets of counterfeit Coartem, a malaria drug made by Swiss pharmaceutical giant [Novartis](#)

NOVN.VX -1.88% AG.



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Counterfeit and Substandard Medicines: A Global Challenge

- Poor quality medicines make up **30 – 50%** of drug sales worldwide
 - Causes > 250,000 preventable deaths annually
- Poor quality medicines account for US\$ 75 billion of US\$ 962 billion global pharmaceutical market
- Poor quality medicines contribute to drug-resistant infection and disease
 - Artemisinin resistant malaria on Thailand-Cambodia border



Two sets of Parameters

- **Affordable**
- **Sensitive**
- **Specific**
- **User-friendly**
- **Rapid and Robust**
- **Equipment Free**
- **Deliverable**

- **Relevant**
- **Sensitive**
- **Inclusive**
- **Effective**
- **Scalable**
- **Sustainable**
- **Innovative**



Existing Field Solutions



GPHF MiniLab®
Field Standard

- Chemical Analysis (TLC)
- Inexpensive
- Bulky (200 lbs) & labor intensive
- Qualitative results



Spectrometers

- Chemical fingerprinting
- Non-destructive
- Semi-quantitative
- High batch variability



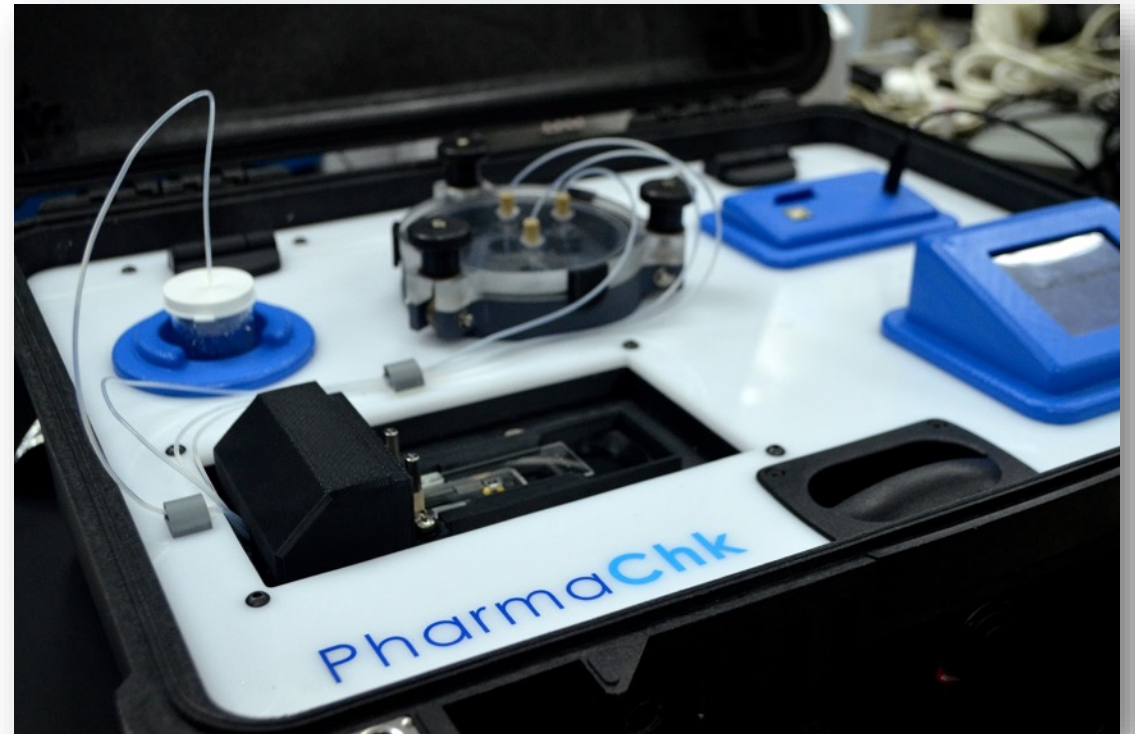
FDA CD3/4

- Packaging Analysis
- Non-destructive
- Not analytical
- Counterfeit-oriented

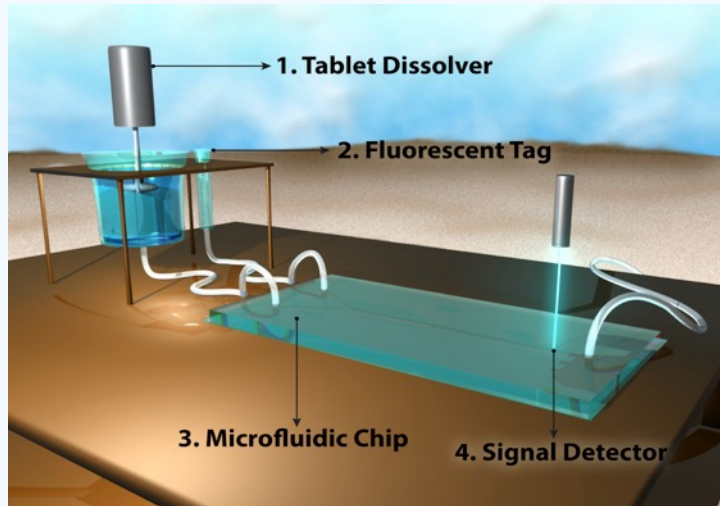
PharmaChk: The Device

Accurately and affordably test the quality of medicines in the field through the quantification of active pharmaceutical ingredient and analysis of dissolution properties

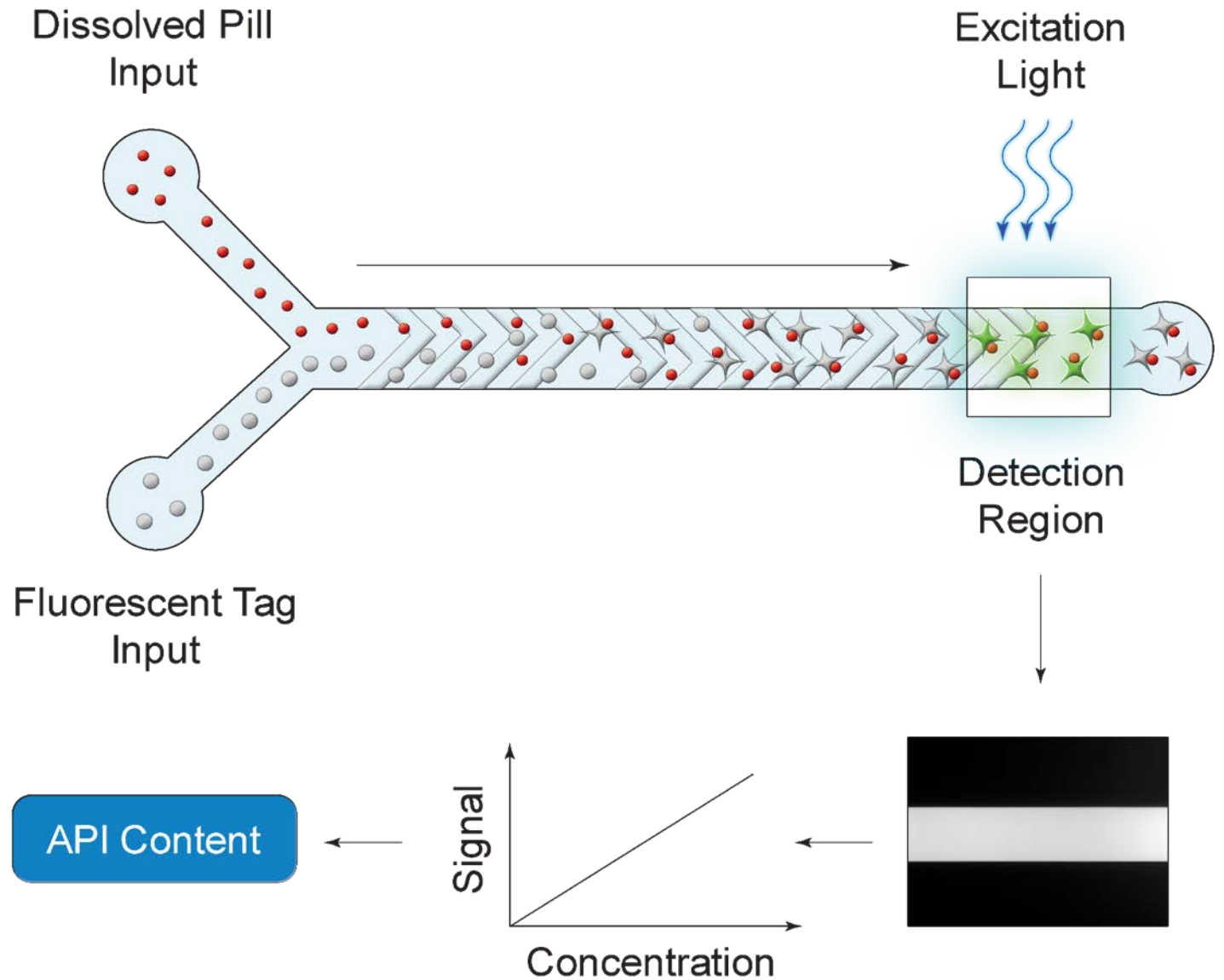
Current Prototype: Test antimalarials and antibiotics



PharmaChk



- Portable platform
- Optical quantification
- Specific chemistry
- No sample preparation



The Access-Quality-Pricing Nexus (Pakistan case study)

- The foundations of Drug Regulatory Authority of Pakistan
- Current focus on pricing and not access or quality
- Impact on discovery, innovation and manufacturing
- The tension between quality and pricing

Table 1

The ratio of population: drug enforcement officer in Pakistan.

Provinces/Territories	Population (million)	Number of drug enforcement officer (full time) in 2017	Ratio population: officer	Difference in actual and WHO recommended ratio (times)
Baluchistan	7.9	PDIs* 57 FIDs** 01	136,448:1	68.2
Punjab	101.1	PDIs 159 FIDs 08	604,790:1	302.3
Sindh	42.4	PDIs 27 FIDs 08	1,211,428:1	605.7
Khyber Pakhtunkhwa	28.2	PDIs 27 FIDs 01	1,000,000:1	500
Gilgit-Baltistan	1.8	PDIs 08 FIDs 01	200,000:1	100
FATA	3.2	PDIs (Nil)*** FIDs (Nil)	Nil	–
Azad Kashmir	4.6	PDIs 08 FID 01	507,777:1	253.8
Islamabad Capital Territory	1.15	PDI 01 FIDs 03	287,500:1	143.7

*Provincial Drug Inspectors.

**Federal Inspector of Drugs.

***Federally Administered Tribal Areas (FATA) Drug inspectors (Total of seven appointments under process).

Open Questions at Access-Quality-Innovation Nexus

- Innovation and the future of local manufacturing
 - API versus finished product imports; biologics manufacture
- The tension between quality and pricing: perception and reality
- Quality as a metric of UHC
- Innovation and the road to UHC