

Deutscher Bundestag

Ausschuss für Gesundheit

Ausschussdrucksache

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ROLE and WORK
of the

Dem Ausschuss ist das vorliegende Dokument
in nicht barrierefreier Form zugeleitet worden.

Unterausschuss Globale Gesundheit,
Deutscher Bundestag
May 13 2024

Dr Johannes Waltz
Chairman Global Pharma Health Fund

MERCK



OVERVIEW

- 1** Introduction and overview of the problem
- 2** Merck, the GPHF and the Merck Minilab
- 3** Conclusions

introduction and overview of the problem

01

The GPHF Minilab

Introduction

“There is no universal health coverage, no health security without access to quality medicines”

Dr Tedros Adhanom Ghebreyesus

“Stopping Murder by Medicine”

Paul Newton, Oxford University, Introducing the Model Law on Medicine Crime

The Scale

- **1% in affluent countries (value about 8 billion US\$)**
- **20% in countries of the former Soviet Union**
- **30% in low-income countries of Africa, Asia and Latin America**
- **50% via illegal online pharmacies, who hide identity and location**
- **1 billion people threatened by fake medicines worldwide per annum**
- **700.000 deaths annually by fake medicines used to treat malaria and tuberculosis**



Substandard and Falsified Medical Products

All therapeutic areas affected

No therapeutic categories
are omitted ...

- Antibacterials
- Antimalarials
- Antiretrovirals
- Vaccines
- Cough syrups
- Antidiabetics
- Cardiovasculars

... from life-saving
to lifestyle medicines



The GPHF and the GPHF Minilab

02



The Global Pharma Health Fund (GPHF)

- **A charitable organization established in 1985 as the German Pharma Health Fund**
- **Mission: Aims to improve healthcare through supporting the fight against counterfeiting using the GPHF Minilab**
- **Close cooperation with international partners like e.g. WHO or US Pharmacopeia**
- **For the last 20 years the GPHF is funded solely by Merck**
- **Project office in Frankfurt**

- **Achieved through:**
 - 1. Manufacture and sale of the GPHF MiniLab**
 - 2. Development of new assays for additional reference agents**
 - 3. “Maintenance”: selling of reagents, standards and consumables**

The GPHF Minilab

What is the GPHF Minilab

- A lab in a case
- Used to detect counterfeit/ fake medicines in LMIC
- Contains nearly 120 reference agents (commonly listed in the Essential Medicines List), reagents, laboratory equipment
- 450 page Manual in English, French & Spanish available online for download
- Weighs 50 kg
- Sold at cost price to LMICs



A key tool in the global fight against counterfeit



- **Currently, more than 1000 GPHF-Minilab™ units are used across more than 100 countries worldwide, covering all continents.**
- **The Minilab uses a semi-quantitative method based on TLC (Thin Layer Chromatography)**
- **The identification of the Active Pharmaceutical Ingredient (API) is based on size, physical and chemical characteristics and properties.**
- **Spots revelation and reading based on the API physical (colour with or without uv light) and/or chemical (chemical reaction) characteristics**

The GPHF Minilab

More than 1000 Minilabs in more than 100 countries

Global use of GPHF-Minilabs for the detection of falsified and substandard medicines

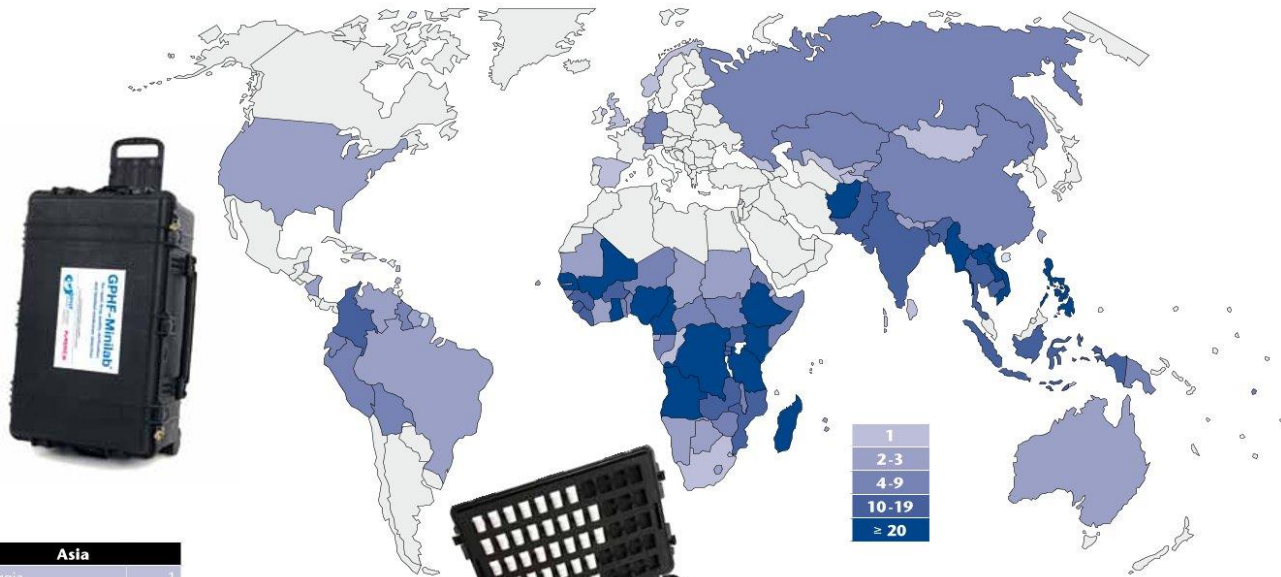
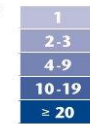
Africa	
Djibouti	1
South Africa	1
Swaziland	1
Cape Verde	2
Congo PR	2
Guinea-Equatorial	2
Lesotho	2
Namibia	2
Botswana	3
Chad	3
Gambia	3
Ivory Coast	3
Mauritania	3
Mauritius	3
Sudan	3
Central African Republic	4
Eritrea	4
Gabun	4
Guinea-Bissau	4
Zimbabwe	4
Benin	5
South Sudan	5
Togo	5
Somalia	6
Malawi	7
Niger	7

Asia	
Burkina Faso	10
Burundi	10
Guinea-Conakry	11
Liberia	11
Sierra Leone	11
Uganda	12
Zambia	14
Rwanda	15
Mozambique	19
Kenya	20
Senegal	20
Mali	21
Angola	22
Cameroon	24
Ethiopia	27
Madagascar	34
Ghana	39
Congo DR	43
Tanzania	57
Nigeria	65
574	

America	
Georgia	1
Mongolia	1
Sri Lanka	1
Tadzhikistan	1
Uzbekistan	1
West Bank & Gaza	1
Belize	1
Grenada	1
Guatemala	1
St. Lucia	1
Virgin Islands (brit.)	1
Nicaragua	2
Surinam	2
Venezuela	3
Ecuador	4
Australia*	4
Taiwan*	5
China*	6
Pacific Island Countries	6
Papua New Guinea	7
Indonesia	9
Philippines	11
62	

Pacific	
Timor Leste	3
Australia*	4
Taiwan*	5
China*	6
Pacific Island Countries	6
Papua New Guinea	7
Indonesia	9
Philippines	11
70	

Europe	
Belgium*	1
Great Britain*	1
Netherlands*	3
Norway*	4
Spain*	6
Switzerland*	9
Germany*	20
Russia*	25
24	



The GPHF-Minilab™
 A mini-laboratory developed by the Global Pharma Health Fund (GPHF) to boost the medicines testing capacity at healthcare providers in developing countries. Focus on priority medicines, for example anti-infectives. Non-sophisticated, affordable and fit for use in the field. Delivered almost 1000 times to more than 100 countries. Minilabs save lives. For more, go to www.gphf.org.



A charitable organisation voluntarily supported by Merck KGaA Darmstadt (Germany)

*For training and demonstration purposes only. Latest update January 2023



Who are our customers



NGOs

- Crown Agents
- Swiss Tropical & Public Health Institute
- Belgium BTC/ CTB
- Germany
- Bill & Melinda Gates Foundation
- Faith based drug supply organisations

Within host countries

- Universities
- Teaching hospitals
- Consumer protection institutions
- Drug procurement agencies

Some basic Facts

- Meets the WHO standards for identifying counterfeit medicines
- Capacity building tool
- Established networks
- Mobile with a strong outer case
- Suited for field work
- Easy to add new APIs (No calibration required by manufacturer)
- Easy to replace any broken parts
- Cannot identify unknown APIs
- APIs and reagents need to be replaced
- Requires end user training



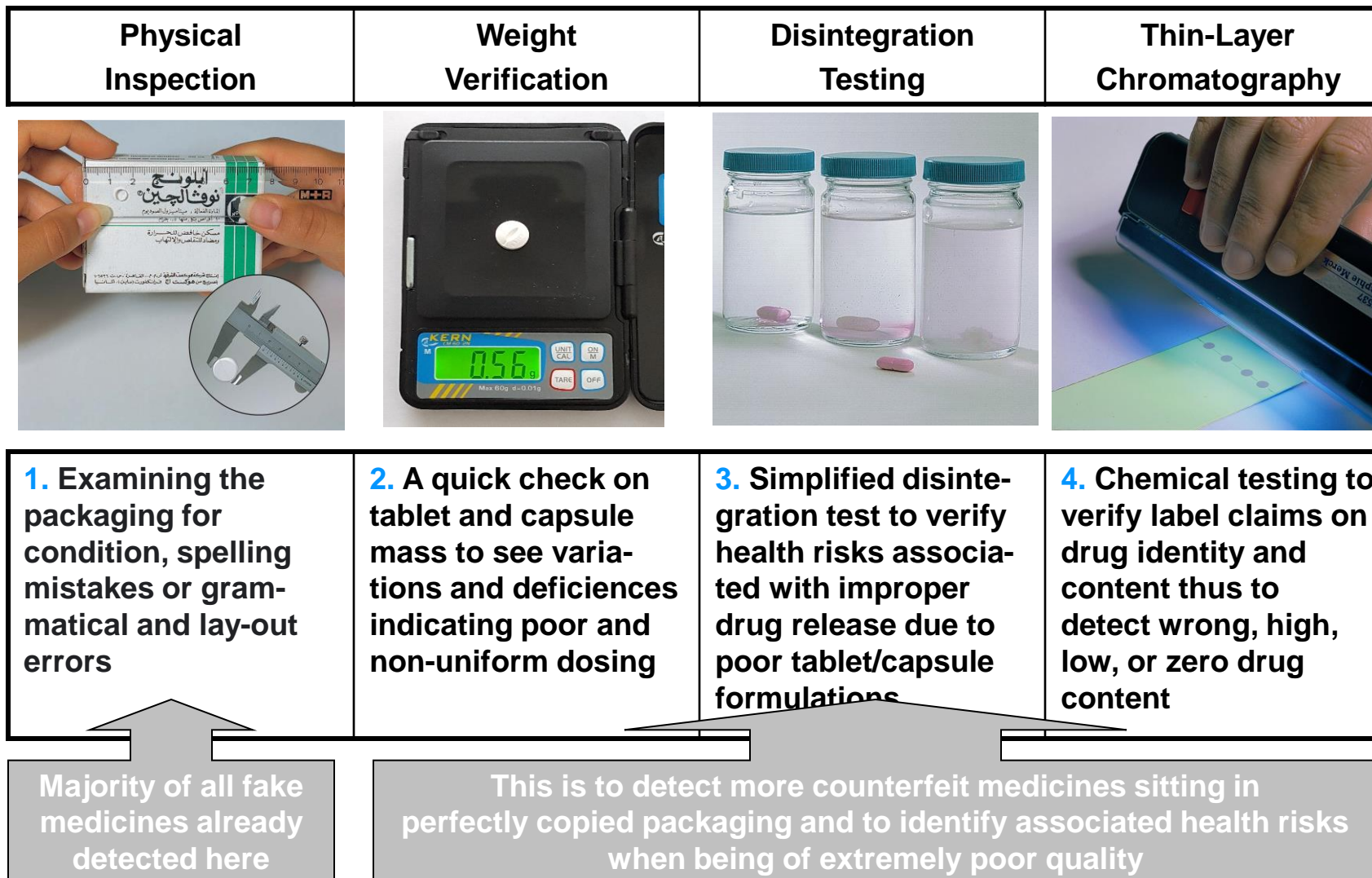
Method inventory 2023

<p>Antibacterial Medicines</p> <p>Amoxicillin, Ampicillin, Azithromycin, Benzylpeni-cillin benzathine/procaine/sodium/potassium, Cefazolin, Cefalexin, Cefixime, Cefpodoxim, Ceftriaxone, Cefuroxime, Chloramphenicol, Ciprofloxacin, Clarithromycin, Clavulanic acid, Cloxacillin, Dapsone, Doxycycline, Erythromycin, Gentamicin, Levofloxacin, Metronidazole, Ofloxacin, Phenoxymethylpenicillin, Sulfa-methoxazole, Trimethoprim, Tetracycline,</p>	<p>Antimalarial Medicines</p> <p>Amodiaquine, Artesunate, Artemether, Atovaquone, Chloroquine, Dihydroartemisinin, Halofantrine, Lumefantrine, Mefloquine, Piperaquine, Primaquine, Proguanil, Pyrimethamine, Pyronaridine, Quinine, Sulfadoxine, Sulfamethoxypyrazine</p>
<p>Antituberculosis Medicines</p> <p>Amikacin, Capreomycin, Cycloserine, Ethambutol, Ethionamide, Isoniazid, Kanamycin, Levofloxacin, Moxifloxacin, Ofloxacin, PAS, Prothionamide, Pyrazinamide, Rifampicin, Streptomycin</p>	<p>Other Medicines</p> <p>Apixaban, ASA, Aminophylline, Amlodipine, Atenolol, Bisoprolol, Captopril, Chlorhexidine, Chlorphenamine, Clomifene, Clopidogrel, Diclofenac, Fluconazole, Furosemide, Glibenclamide, Griseofulvin, HCT, Hydralazine, Mefenamic Acid, Metformin, Methyldopa, Naproxen, Paracetamol, Prednisolone, Rivaroxaban, Salbutamol, Sartans, Warfarin</p>
<p>Anti(retro)viral Medicines</p> <p>Aciclovir, Didanosine, Efavirenz, Indinavir, Lamivudine, Nevirapine, Stavudine, Zidovudine – Oseltamivir, Ritonavir</p>	<p>Anthelmintic Medicines</p> <p>Albendazole, Mebendazole, Praziquantel</p>
<p>Pending Antidiabetics, e.g. Empaglifozin, Gliclazide, Glimepiride, some Gliptins</p>	

113 actives plus their fixed-dose combinations



Includes a range of test methods



conclusions

03

Conclusions

1 The impact of SFMPs globally is vast, affecting uncounted millions of people all over the world

2 Much more needs to be done to start to tackle this huge problem which literally kills patients

3 The GPHF Minilab is one of the most, if not the most, versatile and nimble anti-counterfeiting tools around



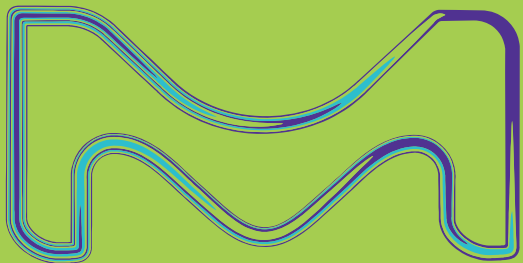
4 It is an affordable mobile solution to detect counterfeit medical products on the ground

5 It makes a substantial contribution to the build up of anti-counterfeiting infrastructure in more than 100 countries

6 However, this contribution can still be increased substantially – we still need more Minilabs to tackle the problem of SFMP

GPHF Minilab

Annex



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Products used for detecting counterfeit medicines¹

Mobile authentication service



- SMS platform
- Text code on packaging or pills
- Verification sent back by governing body

TRUSCAN



- US military invention for non-destructive on the spot identification of medicines
- Uses Raman's spectrometry

Black eye



- Uses infrared technology & non-destructive
- Can identify several APIs* and dosage

Radio frequency identification system (RFIS)



- Tracker of food and drugs from production to the consumer
- Uses electromagnetic fields

*APIs- Active pharmaceutical ingredients

The GPHF Minilab

How to use it

- Operator have to perform basic laboratory techniques, like measure volumes and weighs, prepare solutions, apply samples and perform simple basic chemical reactions
- The result is read and interpreted by the operator
- There are several steps that can influence the outcome, due to high human intervention
- Almost no technology used and no need for power supply to perform the analysis (only 3As batteries)



Spectroscopic devices vs GPHF Minilab^{1,2}

	Pros	Cons
Spectroscopic devices (e.g. Truscan, Black eye)	<ul style="list-style-type: none"> • Non-destructive test methods • Light weight • Minimal end user training • Able to identify unknown APIs 	<ul style="list-style-type: none"> • Relatively costly • In-built library of APIs dependent on device memory • Re-calibration by manufacturer to add new APIs • In-built library of APIs may not be suitable for screening of finished pharmaceutical products • Visual inspection excluded as part of testing process • May not work well under harsh climatic conditions (e.g. Black Eye)
GPHF Minilab	<ul style="list-style-type: none"> • Relatively affordable • Mobile with a strong outer case • Wide range of APIs available as reference samples • Easy to add new APIs (no re-calibration required by manufacturer) • Easy to replace any broken parts • Visual inspection included as part of the testing process 	<ul style="list-style-type: none"> • Destructive testing methods • Requires end user training • Cannot identify unknown APIs • APIs and reagents need to be replaced • Bulky

Competitive analysis

	Pros	Cons
Spectroscopic devices (Truscan)	<ul style="list-style-type: none"> • Non-destructive test methods • Light weight (Truscan) • Minimal end user training 	<ul style="list-style-type: none"> • Relatively costly: \$20 000 • Limited device memory • Calibration by manufacturer to add new APIs • In-built library of APIs may not be suitable for screening of finished pharmaceutical products • Sent back to manufacturer in case of breakage or maintenance • Cannot identify unknown APIs • No quantitative measures can be given
GPHF Minilab	<ul style="list-style-type: none"> • Relatively affordable • Suited for field work • Capacity building tool • Gives semi-quantitative results • After sales service • Mobile with a strong outer case • Wide range of APIs available as reference samples (100) • Easy to add new APIs (No calibration required by manufacturer) • Easy to replace any broken parts • Established networks 	<ul style="list-style-type: none"> • Destructive testing methods • Requires end user training • Cannot identify unknown APIs • APIs and reagents need to be replaced • Bulky