



Falsified Medicines Legislation

What will change for you

Presented by: Katrin Nodop
Compliance and Inspection | European Medicines Agency



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Falsified Medicines Legislation

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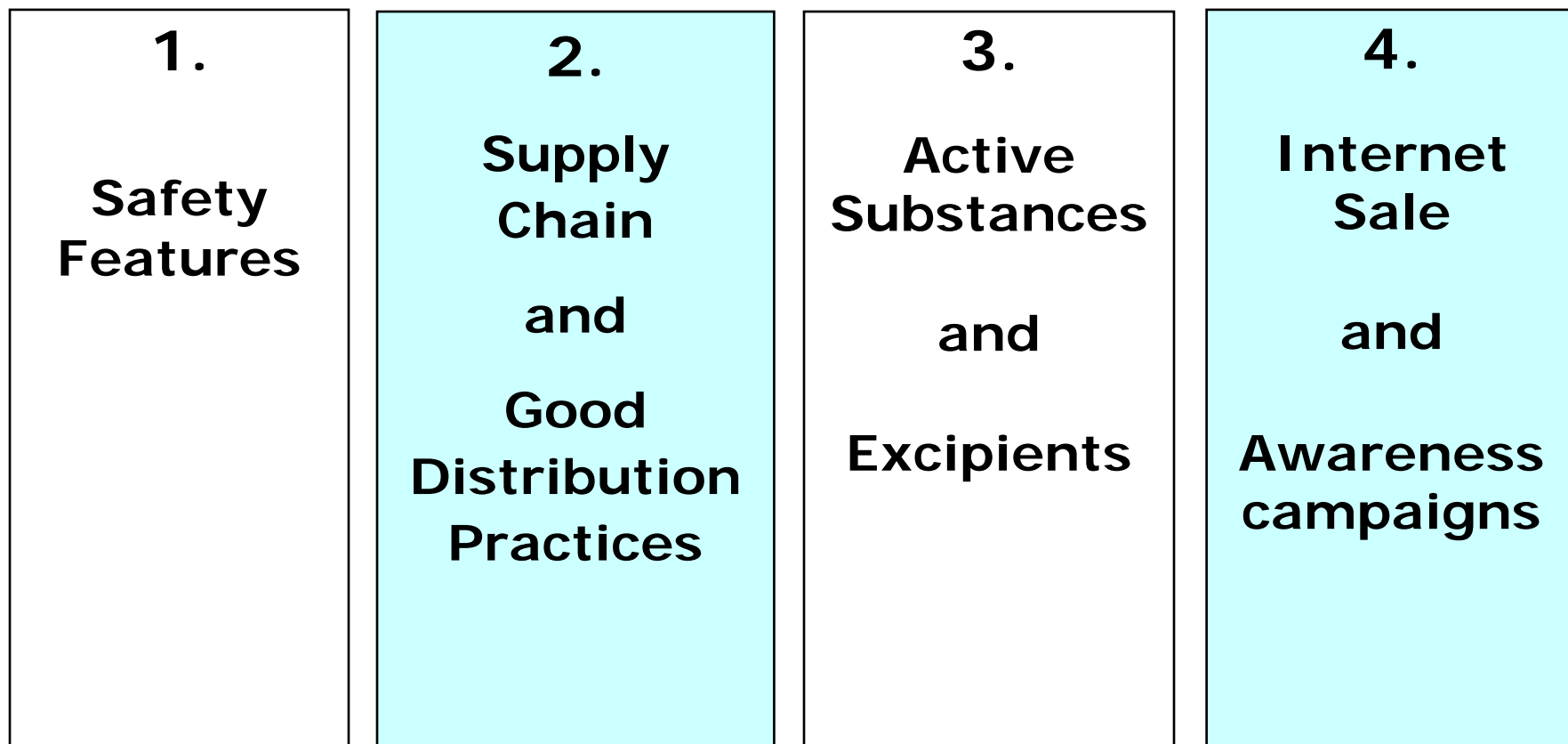
Directive 2011/62/EU published 1 Jul 2011

Amending Directive 2001/83/EC
relating to medicinal products for human use,
as regards the prevention of the entry into the
legal supply chain of falsified medicinal products

Entry into force:	2 January 2013
Active Substance Provisions:	1 July 2013
Common Logo:	12 months after Implementic Act
Safety Features:	36 months after Delegated Act



The fab four - main areas of change





1. Safety Features

For Medicinal Products subject to prescription
with exception – based on risk of falsification

NOT for Medicinal Products without prescription
unless at risk of falsification

List to be established - published by EC



Details Safety Features

Commission to adopt delegated act with the objective of establishing detailed rules for safety features

Characteristics and technical specifications;

Modalities for the verification;

Repository systems holding this information



2. Supply Chain & GDP

Wholesale Distributors increased obligations

Maintain a Quality System

Verification of compliance with GDP of Suppliers

Obligations for export: record keeping

Obligation on distributors to **report** any suspicion of falsification

Definition & specific provisions for **brokers**

MS to maintain **list** of brokers on their websites



3. Active Substances

Direct obligations for manufacturers of AS
Registration of manufactures, importers,
distributors of AS
Mandatory audits

Specific provisions for import of API
Third country listed by Commission or
„Written confirmation“ by third country



4. Internet Sale

Internet Pharmacies to notify to Member State:
Address, website, products offered, display new
EU logo and link to authority's website.

Member States to list authorised internet
pharmacies

Public awareness campaigns on risks of falsified
medicines

EMA to establish website with links to Member
States



Other new measures

Provisions for **introduction** of medicines
(not placed on EU market)

MS shall organise meetings involving
enforcement officers (prevention and
enforcement to combat falsified medicines)

MS NCA to ensure cooperation with customs
authorities



Impact on Regulators

EC, EMA, Authorities in EU and Third Countries

Develop Guidelines / Rules / Formats / Contents

GDP for AS; GDP for finished products;

Risk assessment – GMP for excipients;

Safety features;

Authorisation / Registrations; Certificates;

Inspection Reports;

Assessment 3rd countries API supervision system

Publicly accessible Union Database



Impact on European Commission

adopt detailed rules for safety features in delegated act

adopt by implementing act the technical requirements and design of the common logo

Implementing act detailing requirements for assessment of 3rd countries regulatory framework for AS



Impact on European Medicines Agency

Develop and manage Union Database

Establish form and content of authorisations, registrations, inspection reports, certificates

Cooperate in the coordination of inspections in third countries

Set up website informing on falsified medicines



Impact on Member States Authorities

- consider criteria and the verification to be made when assessing the potential falsified character of medicinal products
- register AS manufacturers importers distributors
- establish publicly available registry for brokers
- enter AS registrations, wholesale distributor authorisation and related information into Union database



Impact on Healthcare Professional - Patients

Reduced risk of receiving falsified medicines
Better informed about falsified medicines
Whitelist of approved internet pharmacies
Recall procedure down to patient level



Joint implementation EC, EMA, MS

GMP for AS; GDP for AS; GDP for products

Assess and verify third countries for AS
regulatory framework

Form and content authorisations/registrations/
inspection reports GxP certificate, non-compl.

Union Database

Website on falsified medicines



Next Steps

- Directive 2011/62/EU implemented by Jan 2013
- Implementing measures and delegated acts by EC
- Safety features (+ >3years);
- AS 3rd country assessments (Jul 2013);
- Implementation plan (priorities)
- Work plan (deliverables);
- Consultations with industry



Work in Progress

- GDP Guideline + provisions for brokers ✓
- Wholesale Distribution Authorisation ✓
- GDP Certificate / Non-Compliance
- GDP Inspection report format
- GL on Inspection process
- GL Serious GDP non-compliance
- Training and Qualification of Inspectors ✓



Challenges

Work load!

Registrations of AS manufacturers

3rd country assessments of AS supervisory systems

Union database development – harmonisation across Europe

LAUNCH EVENT

INTERPOL IS PLEASED TO INVITE YOU TO THE LAUNCH OF THE SONG

"PROUD TO BE"

Yvonne Chaka Chaka featuring Youssou N'Dour

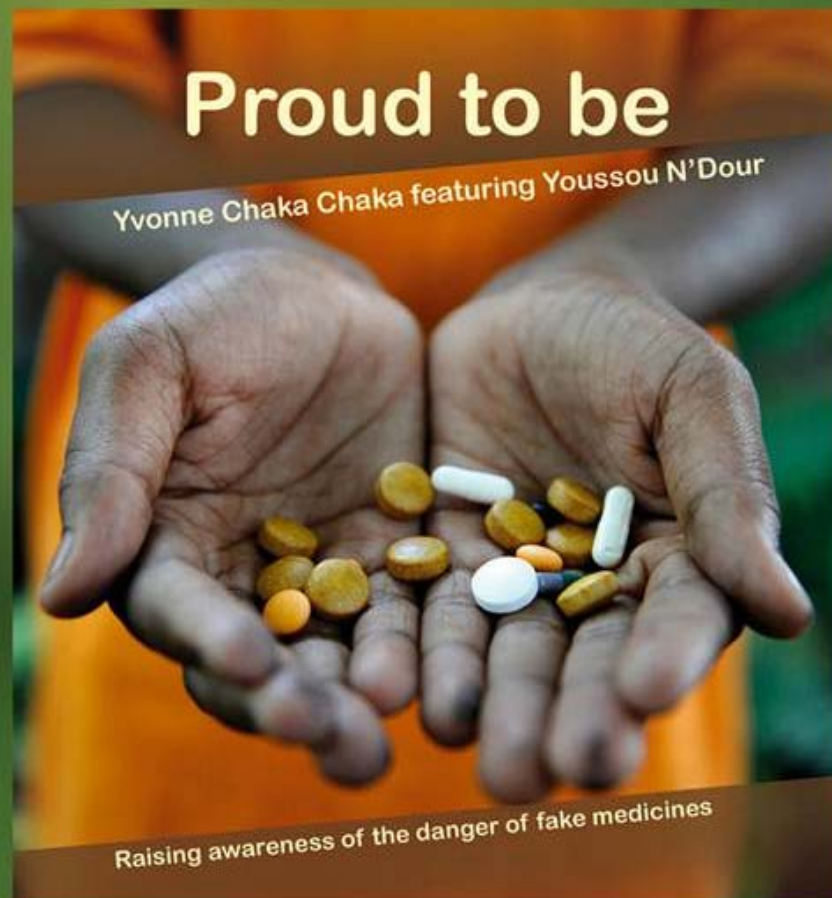
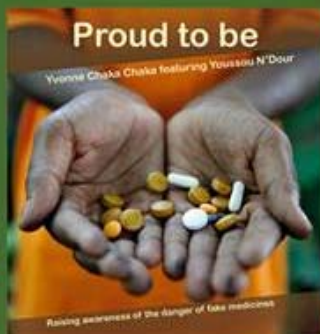
on

Thursday 27 October 2011 at 09:30

In the Hotel Hilton - Nairobi, Kenya

RSVP: Geraldine Opsahl : g.opsahl@interpol.int by 14 October 2011

Tel. +33 4 72 44 76 59



A song to raise awareness about fake medicines

Counterfeit medical products put the lives of people in danger every day around the world. In Africa, counterfeit medicines can represent one-third of the market. Through the song "Proud to be", the world's largest police organization INTERPOL aims to raise awareness worldwide about fake drugs, the criminal networks behind them, and the risks they pose.

This song is a collaboration between INTERPOL and the South African singer Yvonne Chaka Chaka with the remarkable support of the Senegalese musician Youssou N'Dour.



INTERPOL

Special thanks to: The Global Fund to Fight AIDS, Tuberculosis and Malaria; Fondation Chirac; International Institute against Counterfeit Medicines; World Health Professions Alliance; Princess of Africa Foundation; Synergies Africaines.





**Would you purchase prescription only medicine without a prescription?
You are not the only one**

The majority of Brits (60%) are becoming far more trusting of buying goods over the internet than they were 5 years ago...¹

- More than 1 in 7 (15%) UK adults have admitted to purchasing prescription only medicine without a prescription¹
- What they probably don't know is that between 50-90%^{2,3} of all medicines sold on websites which conceal their address are fake – a gamble not worth taking
- 78% of doctors agree that people are risking their health, and potentially even their life by doing this⁴

So what are the real facts?

- Counterfeit medicines can contain harmful ingredients such as rat poison, boric acid and lead based road paint^{5,6}
- They can also contain too little or too much active ingredient – some contain no active ingredient at all^{2,7}
- Fake drugs can cause harm to patients and sometimes lead to death⁷
- It is often produced by people who have no appropriate qualifications in unhygienic surroundings^{8,9}

Think twice about the medicines you buy

Don't bypass the healthcare system to get your prescription only medicine quickly or cheaply – it's not worth the risk

For more information speak to your GP or pharmacist or visit www.realdanger.co.uk



References 1. YouGov Plc data, September 2009. Participants: 2076 adults. 2. WHO and IMPACT factsheet. Counterfeit drugs kill! Last accessed on 13.10.09 from <http://www.gphf.org/Images/downloads/impactbrochure.pdf> 3. In-PharmaTechnologist News. Last accessed 08.10.08 from <http://www.in-pharmatechnologist.com/Industry-Drivers/The-global-disaster-of-fake-internet-pharmacies> 4. Medix UK plc (2009) Market Research Report: Counterfeit Drug Study 5. Solomon, S. BC Woman killed by fake drugs bought online. National Review of Medicine. 2007; 4:13 6. Pfizer data on file 7. http://www.who.int/medicines/services/counterfeit/impact/impactf_5/en/index.html 8. Pfizer data on file 9. European Alliance for Access to Safe Medicines: The Counterfeiting Superhighway, 2008, Medicom.

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European Medicines Agency

7 Westferry Circus
Canary Wharf
London
UK

**Thank you for your
attention!**

katrin.nodop@ema.europa.eu

