



# Quality Medicines Seminar: the example of two NGOs

Tine Demeulenaere

# Presentation Damien Foundation

---

- ▶ An international NGO specialized in TB and Leprosy control
- ▶ Working in 16 countries
- ▶ Mostly support to national TB and leprosy programs – national or at least provincial coverage
- ▶ Big projects in DR Congo, Bangladesh and India
- ▶ Sending medicines (>80% TB medicines) to 6 countries:
  - ▶ DR Congo (most!), Niger, Bangladesh, Comoros, Guinea, Burundi, Rwanda
  - ▶ For this, we have since long an export license for medicines from Belgium
  - ▶ Grouping requests, meds and medical mats and other, per country, under customs in Belgium and sending
- ▶ Buying locally (the exception!): Bangladesh, India, DR Congo
- ▶ About 800.000 euro of medicines and medical material bought per year
  
- ▶ DGD cofinanced in: DR Congo, Bangladesh, India, Burundi, Guinea
- ▶ 320M pop, 230.000 TB, 17.000 leprosy, 5000 Leishmania, 22.000 handicap former leprosy, 2500 MDR-TB patients in supported regions

# Initial Situation 2008

---



**Charter Quality Meds signed, YES, GREAT, FINALLY!!!**



**But how to implement?  
Where is the know-how  
to put into practice the  
audit-threat?  
To select where to buy  
knowingly?  
Exception: WHO-PQ (\$\$  
for some)**

# Than Came Quamed: 20..



- \*Distributors audited**
- \*Database with GMP level of a list of Manufacturers**
- \*Expert HR to put into practice the audit-threat**
- \*Country audits for local purchases**

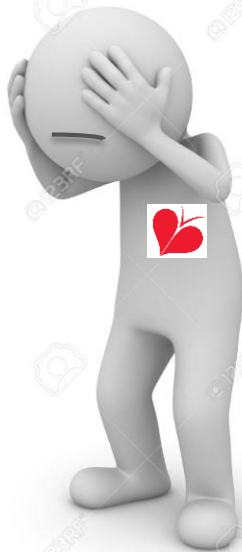
# Happy till... 2016-2017



**Charter Quality Meds**



**Stronger Donor Rules:  
DGD agreement signed  
others**



# Inspection by FAGG (AFMPS)

---

- ▶ Apparently....
- ▶ Having an export license...
- ▶ You are considered a medicine wholesaler
- ▶ Even if you don't sell a thing....
- ▶ And FAGG can inspect you for respect of GDP, even if your meds never enter Belgium...



# Belgian law & EU rules governing procurement & distribution of medicines

**BELGISCH  
STAATSBLAD**

Publicatie overeenkomstig artikelen 472 tot 478 van de programmawet van 24 december 2002, gewijzigd door de artikelen 4 tot en met 8 van de wet houdende diverse bepalingen van 20 juli 2005.

Dit *Belgisch Staatsblad* kan geconsulteerd worden op :  
**www.staatsblad.be**

Bestuur van het Belgisch Staatsblad, Leuvenseweg 40-42,  
1000 Brussel - Adviseur : A. Van Damme

**Gratis tel. nummer : 0800-98 809**

176e JAARGANG

VRIJDAG 22 DECEMBER 2006  
DERDE EDITIE

14 DECEMBER 2006. — Koninklijk besluit betreffende geneesmiddelen voor menselijk en diergeneeskundig gebruik, bl. 74016.



**N. 418**

**MONITEUR  
BELGE**

Publication conforme aux articles 472 à 478 de la loi-programme du 24 décembre 2002, modifiée par les articles 4 à 8 de la loi portant des dispositions diverses du 20 juillet 2005.

Le *Moniteur belge* peut être consulté à l'adresse :

**www.moniteur.be**

Direction du Moniteur belge, rue de Louvain 40-42,  
1000 Bruxelles - Conseiller : A. Van Damme

**Numéro tél. gratuit : 0800-98 809**

176e ANNEE

VENDREDI 22 DECEMBRE 2006  
TROISIEME EDITION

14 DECEMBRE 2006. — Arrêté royal concernant les médicaments à usage humain et vétérinaire, p. 74016.

23.11.2013

EN

Official Journal of the European Union

C 343/1

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES  
AND AGENCIES

EUROPEAN COMMISSION

Guidelines

of 5 November 2013

on Good Distribution Practice of medicinal products for human use

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF>

# Building a Quality System: obligation!



**Quamed**

**Consultants**

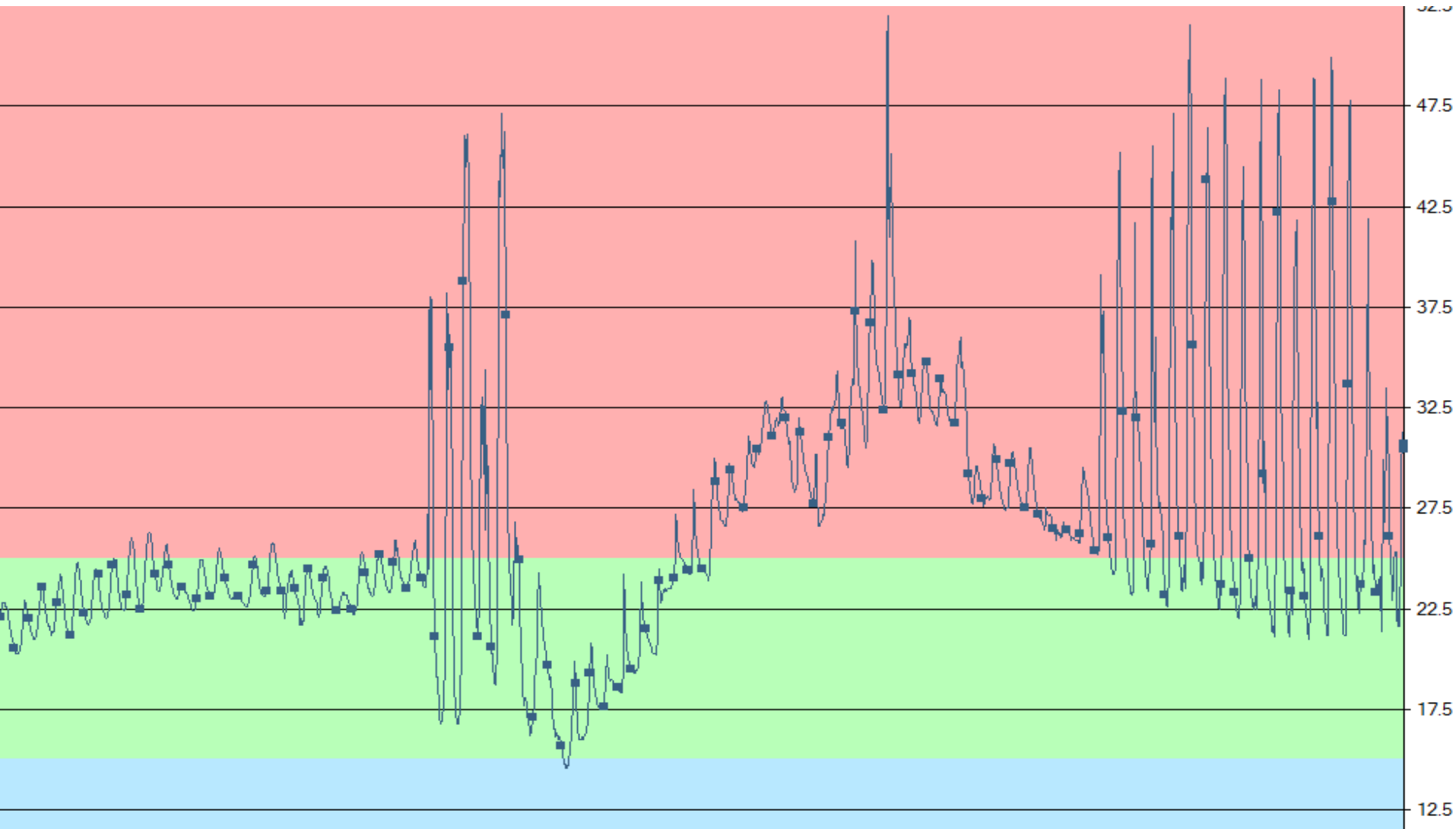
MSF-Supply GDP  
pharmacist  
Quamed & Raffaella  
Consultants  
Volunteer pharmacist



**Progressive Donor  
Rules:  
DGD, others**



# What Next? Temperature Study:



► Indifference kills, Damien Foundation heals

# Help!

---

- ▶ We need heat stable medicines ... tested and stable in tropical conditions!
- ▶ And ...We need a Quamed for medical devices & equipment

foundation  
**damien** 

Indifference kills, Damien Foundation heals

