



Product Development Partnership for better « Access to Medicines » An Example on Malaria

Accès au Médicament
Access to Medicines

Access to Medicines



Access to Medicines at sanofi-aventis

- A fully integrated department covering all skill areas
- Dedicated to develop sustainable programs against diseases that impact the developing and emerging world
- Production facilities all around the world
- Partnerships with public & private national, international organizations





7 priority areas

MALARIA



TUBERCULOSIS



SLEEPING SICKNESS



VACCINES



LEISHMANIASIS



EPILEPSY



MENTAL HEALTH



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An Example on Malaria



Malaria –The context

- **One-third of the world population lives in malaria endemic areas**
- **Approximately 500 million attacks/year**
- **More than 1 million deaths**
Primarily African children < 5 years
- **Major economic impact**
Malaria is a poverty-related disease
Malaria worsens poverty
- **Main problem with treatments: development of resistances**
- **Artemisinin-based Combination Therapies recommended by the WHO since 2001**



DNDi and sanofi-aventis

An innovative partnership

- ▶ **ASAQ = artesunate+amodiaquine in Fixed Dose Combination**
- ▶ **Product development**
 - Formulation developed by DNDi
 - Industrial development program carried out by SA
- ▶ **Drug registration**
 - Drug registered by SA in Morocco (where the product is manufactured) and then in endemic countries
 - WHO prequalification October 2008
- ▶ **Price**
 - « Access to Medicines » pricing policy: tiered-pricing, up to « no profit-no loss » in public sector, NGOs, international organizations...
- ▶ **Non exclusivity of the product**
 - DNDi and SA have agreed not to take any patent covering this FDC

Adapted Medicines

“ASAQ”

FDC* Sanofi-aventis

Infant
(<8 kg)



Toddler
(8-17 kg)



Child
(17-35 kg)



Adult
(>35 kg)

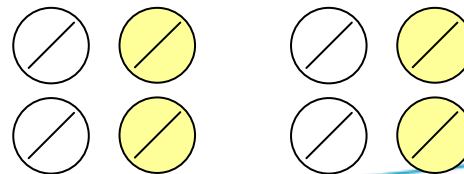
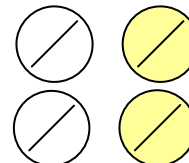
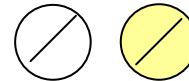


DNDi

Drugs for Neglected Diseases initiative

Artesunate-Amodiaquine

Co-blister



Artemether-Lumefantrine

FDC*

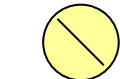
AM

PM

5-15 kg



15-25 kg



25-35 kg



>35 kg



*Fixe Dose Combinaison

sanofi aventis

Because health matters



Coarsucam / ASAQ

- **Adapted** to patient needs of all ages
Four presentations / soluble tablets
- **Simple** as a once-a-day, 1 or 2 tablets, regimen
Age- or weight-based dosing
- **Accessible** as a non-patented drug, at affordable prices in public markets, up to “no profit-no loss” prices
- **Quality**
WHO GMP-certified manufacturing plant
WHO prequalification



Affordable Medicines

Public markets:

Artesunate-Amodiaquine Winthrop®

Tiered-pricing policy up to “no-profit no-loss” price:

- < \$1 adult treatment
- < \$0.50 children treatment



Private markets:

Coarsucam®

\$2 to \$3 Wholesalers' price



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Mission accomplished?

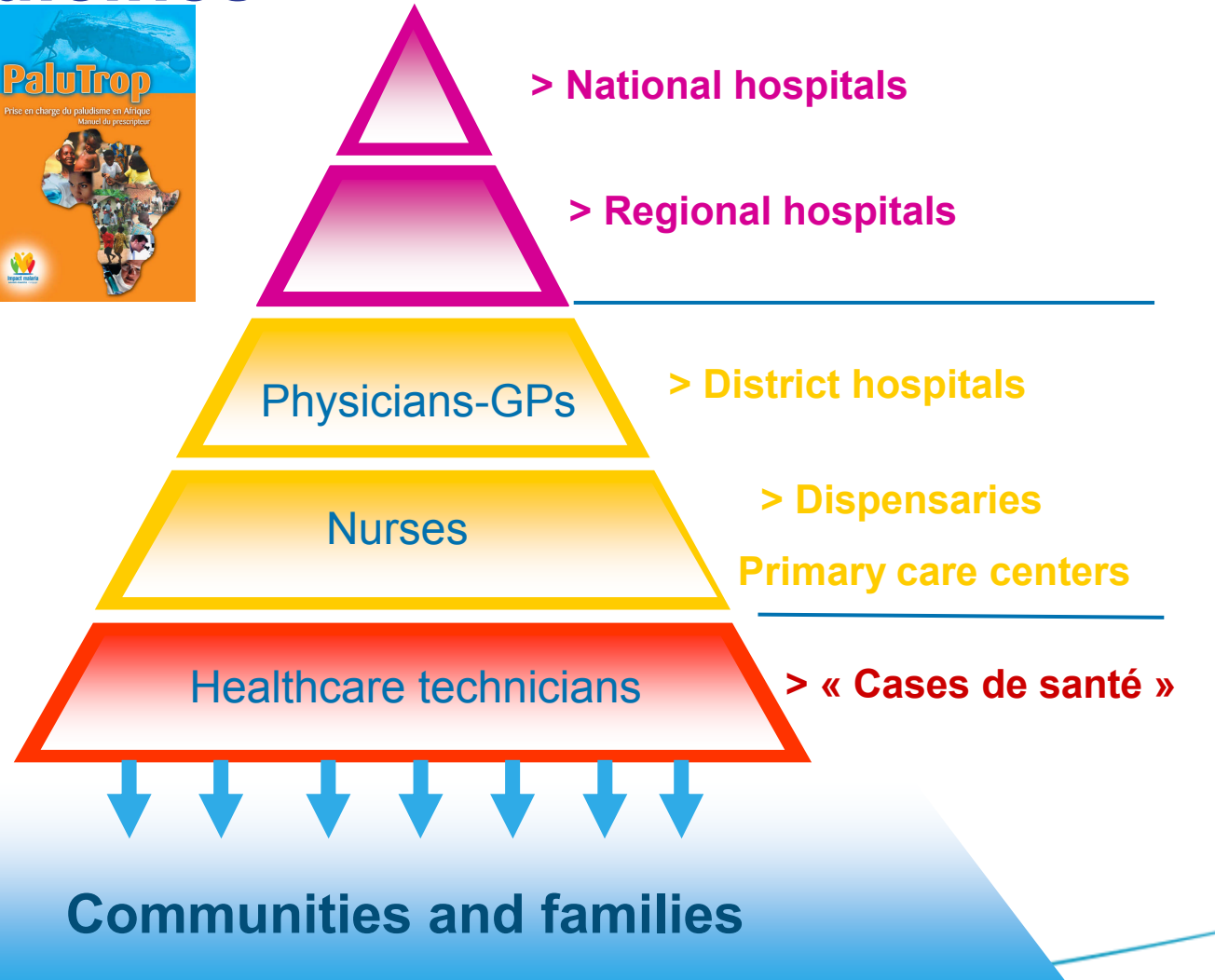
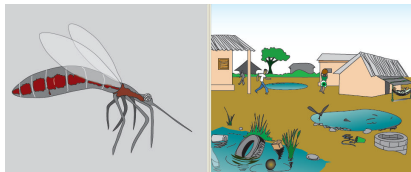
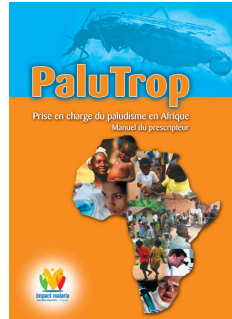
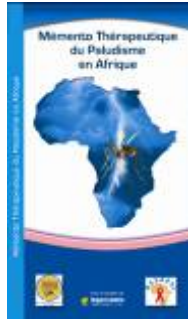
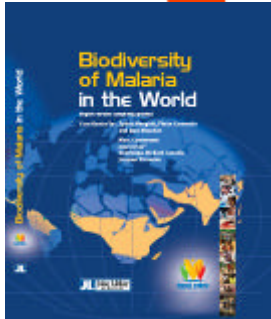


Tools & services for appropriate use of medicines

- **For healthcare professionals:**
medical information on diagnosis and treatment of malaria
- **For communities and families:**
Prevention of malaria: *where does malaria come from ?*
Key messages on medicines (compliance, quality)
- **“Tool Box”** to be adapted by local stakeholders



Tools & services for appropriate use of medicines



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Because health matters



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Bienvenue sur le nouveau site impact-malaria.com

Découvrez le nouveau site Impact-malaria.com entièrement revisité pour vous offrir une information complète et une agréable navigation.

Entre autres nouveautés, un focus sur la formation :

- six modules intégrés
- des exemples d'outils de formation développés avec nos partenaires de terrain
- une tribune scientifique qui donne la parole aux experts du paludisme

Bientôt la Lettre vous alertera sur les événements importants. Inscrivez-vous dès maintenant :

► [Abonnement](#)

L'actualité

25 avril 2009 : Journée mondiale contre le paludisme

A l'occasion de la deuxième journée mondiale contre le paludisme, les pouvoirs publics, entreprises privées, organisations humanitaires et professionnels de santé se mobilisent dans des actions et programmes de sensibilisation.

► [En savoir plus sur l'événement du 25 avril 2009.](#)



Formation de formateurs au Burundi

La première formation de formateurs pour la prise en charge et le traitement du paludisme s'est déroulée du 2 au 4 février 2009 au Burundi.



Formation

Améliorez vos connaissances sur le paludisme avec le module de formation continue de Marcel Hommel

► [Formation médicale continue](#)

Agenda

La liste des congrès et des événements sur le paludisme

► [Agenda des congrès](#)

Newsletter

Bientôt la Lettre vous alertera sur les événements importants. Inscrivez-vous dès maintenant

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Coarsucam / ASAQ « Deployment Monitoring Plan »



Coarsucam / ASAQ « Deployment Monitoring Plan » - Rationale

- **Counterfeits and substandard generics will soon follow ASAQ launch**
Risk of safety issues, rumors, controversies
- **Limited pharmacovigilance and resistance monitoring systems in sub-Saharan Africa**
Limited spontaneous pharmacovigilance reporting
No pharmacovigilance data to be expected from industrialized countries
- **Sanofi Aventis and DNDi have a duty to monitor ASAQ safety, as well as development of resistances during wide-scale deployment**



Coarsucam / ASAQ

« Deployment Monitoring Plan »

↳ Objective :

Gather good quality safety and efficacy data in a variety of malaria transmission settings, through a variety of proactive studies

↳ Methods

Randomized clinical trials (> 4 ongoing studies in Africa)

Comparative 2-years cohort studies (Senegal, Uganda)

Large-scale comparative safety study (1000 patients, Liberia)

Large-scale ASAQ implementation study (15,000 patients, Côte d'Ivoire)



Coarsucam / ASAQ

« Deployment Monitoring Plan »

Objectives

Approx. 20,000 ASAQ patients enrolled

Beyond antimalarials, help build capacity and expertise on novel ways to perform pharmacovigilance in Africa

MMV and DNDi support for “implementation study”

WHO Department of Medicines Policy and Standards: this initiative will set standard for “Risk Management Plans” for future antimalarials



Benefits of PDPs

- ▶ Putting together the strengths of partners, PDPs, focusing resources and competencies, permit to develop faster high quality products
- ▶ Partners must ensure appropriate use of drugs and continued support

**For the benefit of patients
in endemic countries**

**Thank you
for your attention**

