

ASAQ Registration Update as of 17 April 2007

The registration process

- In Morocco, the ASAQ country of origin:
 - undertaken by sanofi-aventis in December 2005
 - approval granted on 1 February 2007
- ASAQ was submitted for registration in 23 sub-Saharan African countries
 - Currently registered in 12 countries:
 - Benin, Burkina Faso, Congo, **Ivory Coast (~20 mil population)**, Gabon, Guinea, **Kenya (AL adopted but big country: ~30 mil)**, Mali, Mauritania, **Democratic Republic of the Congo (~60 mil)**, Togo and Zanzibar.

The WHO prequalification process

- Prequalification dossier submitted 23 February 2007
- Formally referenced on 12 March (dossier numbers MA 56, MA 57 and MA 58)
- As part of the prequalification process, WHO has scheduled the Casablanca (Morocco) production plant inspection for 11-13 June 2007

On 30 January 2007, a **GMP inspection** of the Casablanca production plant was carried out by independent experts appointed by Médecins Sans Frontières.

- No “critical” findings were made.
- The final report will be communicated to UNICEF/WHO.

Finally, an ASAQ application for paediatric use will be filed for inclusion into the July 2007 **WHO Model List of Essential Medicines** Committee review session focused especially on essential medicines for children.

On a quarterly basis, updates will be provided on ASAQ developments:

- Email: info@actwithasaq.org
- Website: www.actwithasaq.org