



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



Agence française de sécurité sanitaire
des produits de santé

AFSSAPS - EGA INFO DAY

| Wednesday, 4 June 2008 |

Paris Marriott Rive Gauche Hotel, Paris, France

Wednesday, 4 June 2008

- 08:00** Registration and Networking Coffee
- 09:00** Welcome Speeches: | Jean Marimbert, Director General, AFSSAPS
| Greg Perry, Director General, EGA
- 09:30** ■ Session 1 - Role of AFSSAPS in Evaluating Generic Medicines
Chair: Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics
**Regulatory and Legal Aspects Related to Generic Medicines Application in France
in View of Implementing New Legislation** | Antoine Sawaya, AFSSAPS
- New Generics Definition,
 - Application under Articles 10.1 and 10.3
 - Interpretation of the Global Marketing Authorisation
 - SmPC Disharmony,
 - Usage Patent,
 - European Reference Product
- Assessment of Generic Medicines Application in France** | Antoine Sawaya &
Heloise Pham, AFSSAPS
- Procedure of Evaluation of Generic Medicines Applications and Involvement of Various
Departments of AFSSAPS
 - Particularities Related to Generic Medicines Applications
- Most Frequent Questions in Deficiency Letters Related to Generics Application**
- Quality Aspects | Anne Gayot, Chairperson of the Generic Working Group, AFSSAPS
 - Bioequivalence Aspects | Patrick Nicolas, Expert of the Generic Working Group,
AFSSAPS
- 11:00-11.15** Coffee Break
- 11:15-13.00** ■ Session 2 - The Role of AFSSAPS in the European Procedures
AFFSAPS Involvement in the European Procedure as the RMS
| Alban Dhanani, AFSSAPS
- AFSSAPS Expectation from the Applicant
 - AFSSAPS Approach to Being the RMS
- Q&A Session with session speakers and representatives of the generic medicines industry



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■ **Session 3 - The Role of AFSSAPS in Supervising the Quality, Safety and Efficacy of Generic Medicines**

AFSSAPS Activities in Controlling the Quality of Generic Medicines on the Market

| *Pierre-Antoine Bonnet, AFSSAPS*

- Programme of Control
- Results
- Further Plans

AFSSAPS' Key Messages to Generics Industry on Inspections | *Pierre-Henri Bertoye, AFSSAPS*

- GCP
- Pharmacovigilance

■ **Q&A Session** with session speakers and representatives of the generic medicines industry

13:00-14.30 **End of Conference and Networking Buffet Lunch**

As places are limited, registration is reserved to EGA members only (max. 2 per company) until 7 May 2008. From 8 May 2008 the remaining seats will be open to other delegates from the generic pharmaceutical industry until 16 May 2008.

For further information and to register on-line, please visit: www.egagenerics.com

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Accommodation form available on:
www.egagenerics.com