2007 EMEA-EFPIA INFO DAY
5 February 2007
09:00 – 17:00 hrs

EMEA
Room 3A
7, Westferry Circus, Canary Wharf, London E14 4HB – Tel. +44.207.418 84 00

Programme

8.30 Coffee

9.00 Welcome and introduction
T. Lönngren (EMEA) and B. Ager (EFPIA)

MORNING SESSION: ACHIEVEMENTS TO DATE
Chairpersons: N. Wathion (EMEA) and S. Forda (Eli Lilly – Chair EFPIA Scientific Technical Regulatory Policy Committee)

PART I: 2006 PERFORMANCE INDICATORS SURVEY

9.30 2006 Analysis of Performance Indicators for Initial Marketing Authorisation Applications
- EMEA results, F. Pignatti (EMEA)
- EFPIA results, E. Ruighaver (Eli Lilly)

10.10 2006 Analysis of Performance Indicators for Type II Variation Applications (Extensions of Indications)
- EMEA results, A. Luis De Lima Marçal (EMEA)
- EFPIA results, Suresh Nair (Abbott) and Marianne Poulmaire (EFPIA)

10.30 Questions & Answers Session
Panel: P. Le Courtois (EMEA), X. Luria (EMEA), F. Pignatti (EMEA), A. Luis De Lima Marçal (EMEA), A. Saint-Raymond (EMEA), S. Nair (Abbott), M. Poulmaire (EFPIA), E. Ruighaver (Eli Lilly)

10.45 Coffee break

PART II: ONE YEAR EXPERIENCE WITH NEW PHARMACEUTICAL LEGISLATION

11.00 Conditional Marketing Authorisations

- EMEA viewpoint, F. Pignatti (EMEA)

11. 20 Risk Management Plans

- Review of experience, S. Blackburn (EMEA)

11.40 EFPIA viewpoint on the EU Risk Management Plan: Does a common standard exist?
B. Arnold (Astra Zeneca)

12.00 Questions & Answers Session
Panel: P. Le Courtois (EMEA), F. Pignatti (EMEA), S. Blackburn (EMEA), A. Humphreys (EMEA), B. Arnold (AstraZeneca)

12.30 Lunch Break

AFTERNOON SESSION: NEW DEVELOPMENTS

Chairpersons: P. Le Courtois (EMEA) and A. Broekmans (Organon - EFPIA Scientific Technical Regulatory Policy Committee member)

PART I: IMPLEMENTATION OF THE PAEDIATRIC REGULATION

13.30 EMEA views on:

- Key steps to be completed by applicants who expect to benefit from the rewards and incentives
- Preparation to be undertaken by applicants for meeting the requirements for new products and line extensions

N. Seigneuret (EMEA)

14.10 Paediatric Project/Development Planning – Key Points to Consider

A. Joos (Merck Sharpe & Dohme)

14.30 Transparency measures foreseen in the Paediatric Regulation

I. Moulon (EMEA)

15.00 Questions & Answers Session

Panel: P. Le Courtois (EMEA), A. Saint-Raymond (EMEA), N. Seigneuret (EMEA), I. Moulon (EMEA), A. Broekmans (Organon), A. Joos (Merck Sharpe & Dohme)

15.30 Coffee Break

PART II: THE INNOVATIVE MEDICINES INITIATIVE

15.45 EMEA viewpoint on the Innovative Medicines Initiative

- Stimulating research and innovation: M. Papaluca-Amati (EMEA)
- Pharmacovigilance aspects: X. Kurz (EMEA)

16.15 EFPIA viewpoint on the Innovative Medicines Initiative

K. Boubekeur (Roche)

16.30 Questions & Answers Session

Panel: M. Papaluca-Amati (EMEA), X. Kurz (EMEA), K. Boubekeur (Roche)

16.45 Concluding remarks

T. Lönngren (EMEA) and B. Ager (EFPIA)

17.00 Close of meeting