



European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 6 September 2006
Doc. Ref.: EMEA/136217/2006

AGENDA

Joint EMEA / Interested Parties meeting on Invented Names

EMA, 11 September 2006

Room 4A, Time 14.00-18.00

Chairman: Noël Wathion

1. Introduction (10')
2. NRG Composition and procedure for checking proposed invented names (20')
3. Criteria addressing safety concerns in proposed invented names (30')
4. Issue of qualifiers and bad connotations in proposed invented names (30')
5. Fixed combinations, extension applications and prodrug containing medicinal products (30')

Coffee Break

6. INN/INN stem concerns in proposed invented names (45')
7. Product specific concerns in proposed invented names (45')
 - Non-prescription medicinal products
 - Generic/hybrid/similar biological medicinal products
8. Conclusions (15')
9. A.O.B

List of Participants:

AESGP: Hubertus Cranz, AESGP Director General; Dr Umberto Filippi, Chair of the AESGP Economic Affairs/PR Committee, Bayer, Italy; Stephen Champion, Chair of the AESGP Regulatory Affairs Committee, GSK Consumer Health; Thomas Thorpe, Novartis Consumer Health, OTC Division; Dr Hermann Kortland, German Self-Medication Association (BAH); Helen Darracott, Proprietary Association of Great Britain (PAGB); Bernard Mauritz, Dutch Self-Medication Association (Neprofarm); George Dokios, Greek Proprietary Association (EFEX)

EFPIA: Catherine Boudot, Laboratoires Servier, France; Hanne Brokopp, MSD, Belgium; Ulf Ellerfelt, Alcon Labs., Sweden; Joanne Green, GSK, UK; Pierre Konings, Akzo Nobel, Netherlands; Alan Hunter, ABPI, UK; Anja Manz, Novartis, Switzerland ; Stefano Marino, Sigma-Tau, Italy; Ann Robins, EFPIA, Belgium; Jürgen Romhild, Boehringer Ingelheim, Germany; Joëlle Saint-Hugot, Sanofi-Aventis, France; Gordon Wright, Trade Mark Attorney with Elkington and Fife; Simon Reeves, Astra Zeneca, UK; Maria Fernandez-Marques, Pfizer, Germany

EGA: Michael Banks, Teva Europe; Mary Smillie, Teva UK; Michel Mikhael, Ranbaxy

EMEA: Noël Wathion, Tony Humphreys, Zaide Frias, Sarah Faircliffe, Sophie Dourdin

Member States representatives: Karl Haidvogel (AGES, AT); Kristina Bech Jensen and Mette Tranholm Hansen (DKMA, DK); Anna Dobson (NIP, HU); Sarah Beesley (IMB, IE); Daniela Nicolescu (ANM, RO); Milada Sabatova and Lucie Doubravova (SIDC, CZ); Adrian Evans (MHRA, UK); Magdalena Leszczynska and Pawel Radomski (URPL, PL); Dominique Westphal (PEI, DE); Tatjana Aune (NOMA, NO); Virginie Bacquet (AFSSAPS, FR); Austrine Augaityte (SMCA, LT); Julia Kovacikova (SIDC, SK); Brynjar Orvarsson (IMCA, IC); Dina Lopes and Francesca Cardoso (Infarmed, PT); Dino Soumpasis (BfArM, DE)