20 March 2012
EMA/869780/2011
Human Medicines Development and Evaluation

Programme - EMA Workshop: Ensuring safe and effective medicines for an ageing population

22-23 March 2012: European Medicines Agency, 7 Westferry Circus, Canary Wharf, London E14 4HB, UK

Please Note: The workshop is now fully subscribed for attendance in person. You can follow the meeting in real time online through this link https://ema.adobeconnect.com/_a756096591/geriatrics. For technical issues with the broadcast please email: GeriatricsITSupport@ema.europa.eu Alternatively, the workshop will soon be published on our video on demand for future viewing.

Workshop general objectives:

- Present and discuss the EMA geriatric medicines strategy and related activities
- Provide an opportunity to highlight synergy areas between stakeholders
- Offer a sounding board for the actions undertaken by and expected from EMA and its committees by stakeholders
- Identify gaps in the strategy, and finding a common understanding of the priorities for action in the area

The sessions are designed around the main themes of the EMA geriatric medicines strategy, and time will be allowed for discussion with the attendees.

Scope:
The fastest-growing segment of the total population is the oldest old—people 80 and over. To address this challenge, action in the geriatric field is a priority in the EMA Road Map 2015 and CHMP work-programme 2011-13. The organisation of this workshop is part of the EMA geriatric medicines strategy, involving stakeholders to discuss the initial steps and explore future directions.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Who will attend?
The presentations and discussions will include experts and impacted stakeholders in the regulatory field, EU Public Bodies, Academic researchers; Patients representatives; Healthcare professional representatives; Pharmaceutical industry representatives.

Programme Coordinator
Francesca Cerreta (Francesca.Cerreta@ema.europa.eu)

Time	Draft Programme	Presenter
22 March 2012		
8:30-9:00	**Opening Remarks and Keynote speeches**	Francesca Cerreta, *EMA* Dagmar Roth-Behrendt, *Member of the European Parliament* Guido Rasi, *EMA Executive Director*
9:00-10:15	**Session 1: Healthy Ageing and Medicines**	**Chair:** Dagmar Roth-Behrendt, *Member of the European Parliament* **Co-Chair:** Manuel Haas, *EMA*
	• Innovation and Partnership for Healthy Ageing	Maria Iglesia-Gomez, *DG SANCO – European Commission*
	• The EMA Geriatric Medicines Strategy	Francesca Cerreta, *EMA*
	• The Patient's Perspective of Ageing	Barbro Westerholm, *AGE Platform*
	• The Industry's Views on Geriatric Medicines	Jean-Pierre Lehner, *Sanofi*
10:15-10:35	**Coffee-Break**	
10:35-13:00	**Session 2: Demonstrating Safety and Efficacy in the Older Population**	**Chair:** Eric Abadie, *EMA CHMP Chair* **Co-Chair:** Tomas Salmonson, *EMA CHMP Vice Chair*
	• The BASE Berlin Study	Elisabeth Steinhagen-Thiessen, *EGZB*
	2.1 Pre authorisation	
	• ICH E7 requirements and how they are translated in practice	Kristina Dunder, *MPA, Sweden*
	• Elderly Patients and Clinical Trials – EMA Notes for Guidance	Bertil Jonsson, *EMA SAWP Vice Chair*
	• Can PK and Modelling help?	Terry Shepard, *MHRA, UK*
	• Modelling and Simulation - A Company's view	Eva Bredberg, *Astrazeneca, EFPIA*

Time	Draft Programme	Presenter
	2.2 Post Authorisation	
	• How To Get Better Data On Medicines Post Licensing	Thomas MacDonald, *University of Dundee, ENCePP*
13:00-14:00	**Lunch**	
14:00-15:30	*2.3 Endpoints and their relevance to older people*	
	• Cancer and Palliative care and work of EORTC	Ulrich Wedding, *EORTC*
	• Endpoints and indications for the older population	William Evans, *GlaxoSmithKline, EFPIA*
	2.4 Are clinical trials in polymedicated or frail patients realistic? How can we obtain data in these patients?	
	• Frailty: Challenges and Possible Solutions	Niccolo Marchionni, *University of Florence, EMA GEG Chair*
	• The Cluster Medicines Approach: Evaluating the feasibility of RCTs in elderly with multimorbidity	Alessandra Marengoni, *Karolinska Institute, Sweden*
	• The Industry's views on "older old" patients	Susanna del Signore, *Sanofi, EFPIA* Philippe Guillet, *Sanofi, EFPIA*
15:30–15:50	**Coffee-Break**	
15:50-17:10	*2.5 Practical proposals on recruitment improvement*	
	• Increasing enrolment in Clinical Trials and the PREDICT Study	Antonio Cherubini, *INRCA, Italy; EMA GEG*
	• Involving Older People In Medical Research	James Goodwin, *AGE UK*
	• Efficacy and Effectiveness models	Graziano Onder, *Univ. Catt. Del Sacro Cuore*
	• Proposal for guidance on medical research for and with older people in Europe	Florian Von Raison, *EFGCP*
	• Practical proposals on recruitment improvement: R&D approach and focus on possible bottleneck issues	Brigitte Stemper, *Bayer Pharma AG, EFPIA*
17:10-18:30	**Roundtable**	

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8:30-10:30	**Session 3: Pharmacovigilance in the Elderly**	**Chair:** June Raine, *EMA PhVWP Chair* **Co-Chair:** Peter Arlett, *EMA*
	• Medication errors and STOPP-START criteria	Denis O'Mahony, *University College Cork*
	• Predictors of outcome and Renal clearance	Ulf Bergman, *Karolinska Institute, ENCePP*
	• Considerations from a NCA and from the iPhVWP	Dolores Montero, *PhVWP, AEMPS*
	• Signal detection and EudraVigilance	Georgy Genov, *EMA*
	• Risk Management Planning in relation to mature patients	Stella Blackburn, *EMA*
	• Pharmacovigilance in Older Patients, Industry's Perspective	Michael Richardson, *Bristol-Myers Squibb*
10:30-10:50	**Coffee-Break**	
10:50-12:30	**Session 4: Adherence and Formulation Issues in the Elderly**	**Chair:** Alexis Nolte, *EMA*
	• Formulations, Packaging and medication practices Considerations	Michael Theodorakis , *EMA GEG* Adalsteinn Gudmundsson , *EMA GEG*
	• Industry Perspective on Formulation and Packaging Considerations	Ron Ogilvie, *Pfizer*
	• What do we need to consider to ensure medication adherence of older adults?	Sven Stegemann, *Capsugel*
	• Lessons learned from paediatric medicines	Diana van Riet-Nales, *QWP, MEB, The Netherlands*
12:30-13:30	**Lunch**	
13:30-14:50	**Session 5: Providing information to the older population**	**Chair:** Juan Garcia Burgos, *EMA* **Co-Chair:** Barbro Westerholm, *AGE Platform*
	• Understanding the needs of older people	Jean-Pierre Baeyens, *EMA Healthcare Professionals' Working Group*
	• A NCA analysis of approval documents	Paul Jansen, *Medicines Evaluation Board*

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	• How can SmPC and EPAR Information contribute to safe and effective use of medicines in the older Population?	Laurent Brassart, *EMA*
	• Package leaflet initiatives	Alexios Skarlatos, *EMA*
	• Industry Perspective on Information to Patients and Carers	Lisette Vromans, *Merck Sharp & Dohme*
14:50-15:30	**Conclusions**	