EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 November 2013
EMA/291054/2013
Human Medicines Evaluation Division

Agenda – Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem

8 November 2013, London
09:00 – 17:00 (UK time) (room 3A)

Time	Agenda	Speaker
09:00-09:10	Welcome and Introduction	European Medicines Agency (EMA)
09.10-09.30	**The European Antimicrobial Resistance (AMR) strategy** Presentation by Directorate General for Health & Consumers (DG SANCO)	A. Rys, European Commission (EC)
	Session 1	
	Approval of new antibacterials	Chairs A. Rys, EC / E. Alteri, EMA
09.30-09.45	- The regulatory framework in the European Union (EU) for approval of new antibacterials: underlying principles, available options, impact on development of new, effective antibacterials and considerations to have rapid authorisations	M. Powell, Infectious Disease Working Party, EMA
09.45-10.00	- The regulatory framework in the USA for approval of antibacterials: available regulatory options and initiatives to stimulate development of new antibacterials	A. Jezek, Infectious Diseases Society of America (IDSA)
10.00-10.10	- The impact of re-imbursement policies on prudent use, the availability of new antibacterials in Member States and the pipeline of new antimicrobials	A. Schuurman, Dutch Healthcare Insurance Board (CVZ)
10.10-10.20	- The perspective of pharmaceutical industry how regulatory framework could be better used to bring new antibacterials to the market and further streamlined	B. Eisenstein, Cubist
10.20-11.15	Open discussion	

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Time	Agenda	Speaker
11.15-11.35	Coffee break	
	Session 2	
	Encouraging appropriate use of antibacterials	Chairs J. Ryan, EC / M. Cavaleri, EMA
11:35-11:45	- The use of antibiotics in humans in the EU – assessing the community and hospital settings	A-P. Magiorakos, European Centre for Disease Prevention and Control (ECDC)
11:45-11:55	- Improving and harmonising the Summary of Product Characteristics and the conditions for use - current use of legal tools and future perspectives	R. Botgros, EMA
11:55-12:05	- 'One Health – the need for coordinating prudent use of similar antimicrobials in human and veterinary medicine'	D. Mackay, EMA
12:05-12:15	- The view of Member States health authorities on the enforcement of EU rules, off-label use of antimicrobials, the impact of guidelines and stewardship programmes and the use of surveillance systems of antibiotic use	H. Hurts, Dutch Ministry of Health, Welfare and Sport
12:15-12:25	- The implementation in practice of EU rules on prescription and retailing of antibacterials- challenges for implementing rules and encouraging prudent use and considerations how to optimise practises	J. Chave, Pharmaceutical Group of the European Union (PGEU)
12:25-13:10	Open discussion	
13:10-14:10	Lunch break	
	Session 3	
	Research and development	
14:10-14:20	- EU Research and Development (R&D) and the impact on regulatory aspects	Chairs A. van Hengel, Directorate-General for Research & Innovation (DG RTD) / H. G. Eichler, EMA
14:20-14:30	- EU funded research projects and the link with the authorisation of new antimicrobials	A. van Hengel, DG RTD
14:30-14:40	- The Joint Programming Initiative on AMR: How to bring new antibacterials to patients.	H. Goossens, University of Antwerp
14:40-14:50	- The perspective of pharmaceutical industry what role public-private partnerships can play in tackling antimicrobial resistance and the link between new business	J. Rex, AstraZeneca

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14:50-15:00	model and regulatory framework - Current involvement of EMA in R&D and future perspectives	M. Cavaleri, EMA
15:00-15:45	Open discussion	
15:45-16:00	Wrap up and conclusion of the meeting	A. Rys, EC