



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2013
EMA/673870/2012

Agenda of the paediatric anticoagulation therapy expert meeting

06 November 2012, EMA meeting room 2G, 08:00-18:30

| Item | | Speaker | Time |
|---|--|----------------|-------|
| Introduction | | | |
| 1. | Arrival and registration | | 09:00 |
| 2. | <ul style="list-style-type: none">• Welcome;• Introduction of participants;• - Objectives of the expert meeting. | Dirk Mentzer | 09:30 |
| 3. | <ul style="list-style-type: none">• Declaration of conflict of interest;• EU Paediatric Regulation. | Thorsten Olski | |
| 4. | <ul style="list-style-type: none">• Recent decisions on PIP applications (new products);• Problem statement. | | |
| Discussion of questions for the expert meeting | | | |
| 5. | Priorities of conditions / products: <ul style="list-style-type: none">• Unmet medical needs in children;• Need for more study data;• Priorities for drugs to be studied for anticoagulation. | All | |
| 6. | General investigation strategies: <ul style="list-style-type: none">• Need for specific investigations for clinical settings (treatment, prevention, ...);• Requirements for PK-PD-data;• Extrapolation (between patient populations, between products). | All | |



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|-----------------|--|----------------------------|------|
| 7. | Clinical trial design: <ul style="list-style-type: none"> • Mistakes (by previous experience) to avoid; • Choice of endpoints; • Superiority/non-inferiority design, powering of studies; • Choice of active comparator. | | |
| Outcomes | | | |
| 8. | <ul style="list-style-type: none"> • Summary of preliminary outcomes; • Discussion. | D. Mentzer Panel | |
| 9. | Wrap-up / consensus | | |