

Implementation of Article 29 EU Decisions

Shirley Norton, UK

Article 29 of the Paediatric Regulation

- CHMP opinion and Commission Decision on line extension or variation application qualifying under Art 8 (new indication, pharmaceutical form, route of administration)
- Applies to Dir 2001/83 authorisations - DCP/MR and national products
- Restricted to part of SmPC being varied (including consideration of supporting data e.g. Module 3)

Article 29 procedures to date

- 5 plus 1 anticipated
- **Cozaar** EU Decision Jan 2009 (partial compliance); new pharm form
- **Arimidex** EU Decision Nov 2009; variation
- **Diovan** EU Decision Apr 2010; extension for new pharm form and variation for paediatric indication
- **Lipitor** EU Decision ; Jul 2010, extension for new pharm form and variation for paediatric indication
- **Xalatan**, CHMP Opinion Jul 2010, variation for new paediatric indication

Lessons learned from our experience so far

Consistent approach needed from all MS

CMDh response:

- CMDh Recommendations for implementing Commission Decisions
- Feb 2009, under revision

Need for clarity on compliance and compliance statement

CMDh response:

- Guidance published
- Template available for compliance statement to be attached to MA
- RMS to lead
- Welcomed by patent offices as evidence of compliance

New Variations Regulation Jan 2010 – implementation of Art 29 EU Decision is unforeseen variation

CMDh response:

- CMDh Art 5 procedure recommended Type IB as default (TIB C.I.1z)
- Interim position – situation under review

CMDh Recommendations under revision

- New guidance on implementation by variation
- Recommendation for early liaison between MAH and RMS between CHMP opinion and EU Decision
 - Agreement of SmPC and other product information
 - National translations
 - Agreement of national follow-up measures and risk management plan recommended by CHMP
- Accommodates need for MS to implement EU Decision within 30 days