CMDh – Coordination Group for Mutual Recognition and Decentralised Procedures – Human

Anne Ambrose - MHRA

Approval Procedures

- **Centralised Procedure** – application to EMA and 1 authorisation valid through EU
- **National Procedure** – single procedure to an NCA
- **MRP** – Mutual Recognition of a nationally authorised product in the RMS
- **DCP** – Decentralised Procedure– Application to RMS and CMS(s) at the same time.
- **MRP & DCP** – products remain NAPs – but remain harmonised through subsequent MR procedures

CMDh
Coordination Group for Mutual Recognition and Decentralised Procedures – Human

- 1995 – MRFG – Informal group of HMA
- 2005 – CMDh established under revised Pharmaceutical Legislation (Directive 2001/83/EC)
- 2012 – Responsibilities of CMDh extended under new PhV legislation
- 2013 – CMDh responsibilities further extended

CMDh – Specific legal tasks

- Aim to solve disagreements on the grounds of potential serious risk to public health between MS in Mutual Recognition and Decentralised Procedures
- Examination of questions relating to pharmacovigilance (Art. 107c, 107e, 107g, 107k and 107q of Directive 2001/83) – (Referrals, PSURs, PASS involving nationally authorised products only)
- Examination of questions relating to variations
- Laying down a yearly list of products for SmPC harmonisation

CMDh – Mission

- Aim for consensus and avoid referrals to CHMP other than in exceptional cases of disagreement on the grounds of “potential serious risk to public health”
- To ensure consistency of standards and good quality decision making across the EU in the interests of public health
- Achieve harmonisation of SmPCs of nationally authorised products
- Present a harmonised view on the interpretation of Directives and Regulations in order to facilitate implementation and finding solutions

CMDh – Membership

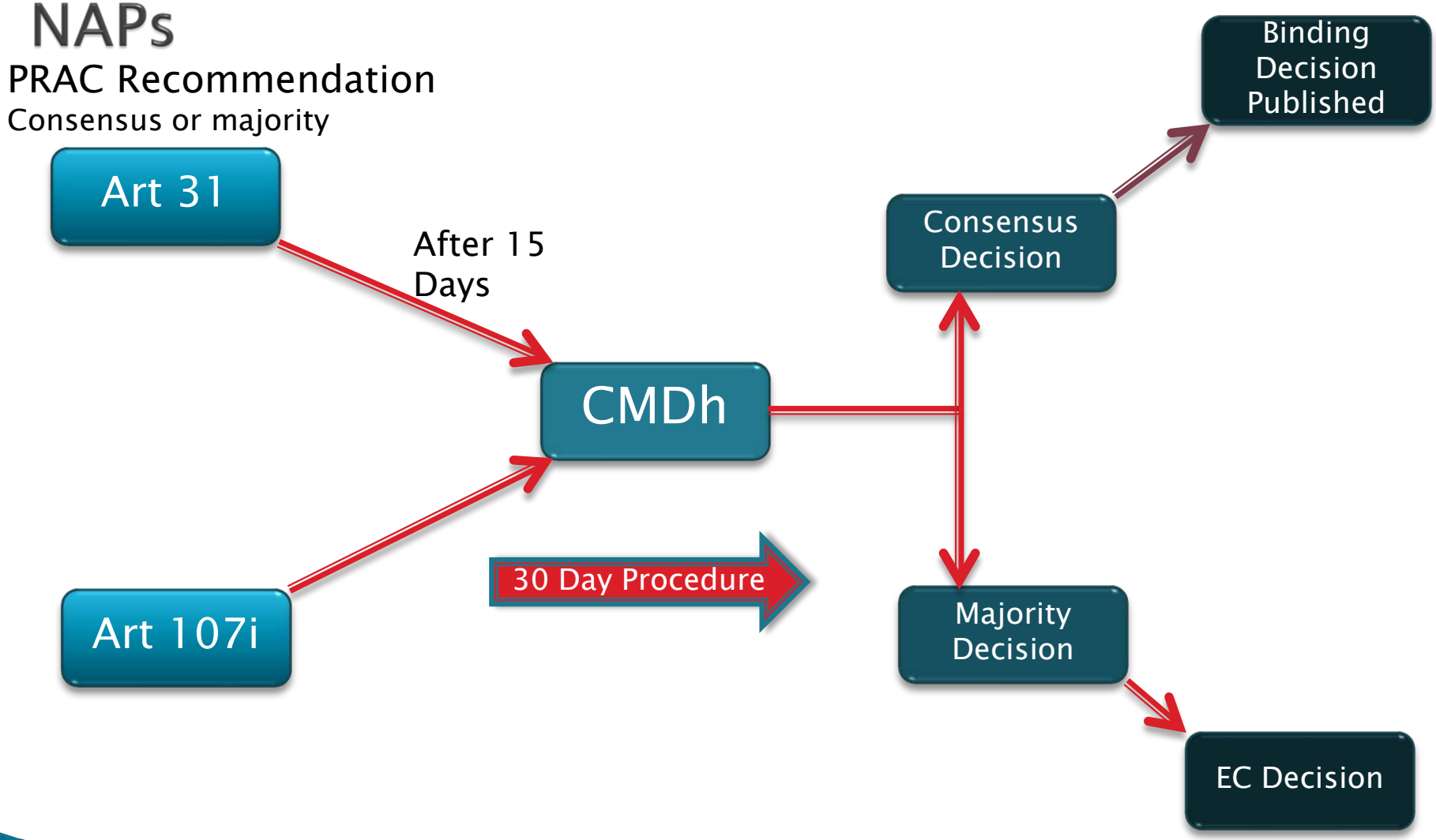
- Chairperson – Peter Bachmann (DE)
- Vice-chairpersons – Christer Backman (SE) and from the MS that holds the presidency of the EU – currently LV from 1st Jan 2015, (LU from 1st July).
- Membership – one delegate per Member State and one alternate
- EEA representatives from NO, IS, LI – voting restrictions
- Observers – EC and accession countries

CMDh Working Parties

CMDh – Decision Making Process Referrals– NAPs

PRAC Recommendation

Consensus or majority



CMDh – Recent Safety Referral Activities

- **Hydroxyzine-containing medicines- Reduction in dose to minimise the risk of effects on heart rhythm- Article 31**
  - *Agreed by consensus to update product information*
  - *Clarification on dosage for paediatrics under 18 years weighing more than 40Kg*
  - *Recommendation that suitable administration devices should be provided for liquid formulations*

- **Codeine-containing medicinal products for the treatment of cough or cold in paediatric patients- Article 31 Referral**
  - *Agreed by consensus with PRAC Recommendation to a contraindication in children below 12 years and not recommended in children and adolescents between 12 and 18 years*
  - *Minimisation of risk accidental overdose for oral liquid products – consider use of child resistant containers*

- **Ibuprofen- and dexibuprofen-containing medicines- Cardiovascular Risk- Article 31**
  - *Agreed by consensus to product information updates regarding the CV risk of high doses*
  - *Practical implications of implementation – could the implementation be phased?*

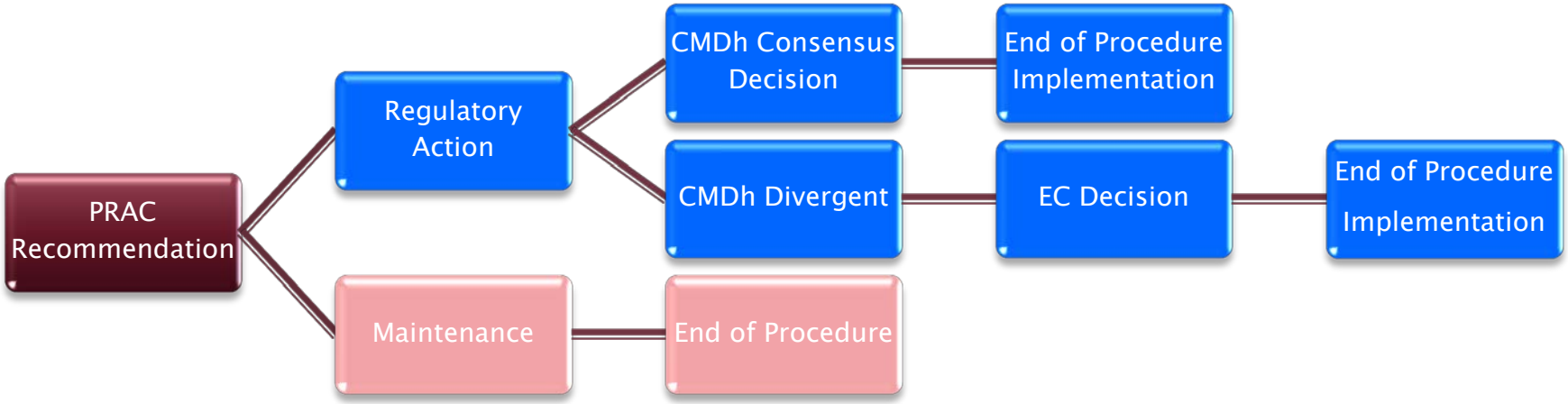
PRAC Requests for Advice

- PRAC Signal assessment on cardiovascular risk of medicines containing high levels of sodium (>17mmol)
- PRAC recommendation regarding signal assessment on accidental overdose with fentanyl patches – improving visibility

CMDh – Clarification and Guidance for Nationally Authorised Products

- **Implementation of the Art 31 referral on polymyxin containing products**
  - *CHMP Review of safety and effectiveness to ensure the safe use in treatment of serious infections that are resistant to standard antibiotics*
  - *CHMP recommendation that IV products could also be administered by intrathecal and intraventricular routes*
  - *Some IV products not suitable for administration by the new routes*
  - *Advice on updates needed to the product quality dossier to implement the intrathecal and intraventricular*

PSUR –Decision making process for single assessment procedures only including NAPs



CMDh – PSUR Decision

- May 2015 – First decision on a PSUR single assessment procedure, with PRAC recommendation concerning NAPs only
- Atenolol/Chlortalidone containing medicines
- Recommendation to update the product information to include 'Lupus- like Syndrome'

Further Information

- http://www.hma.eu/cmdh.html