



Joint PCWP/HCPWP meeting Feedback from PRAC

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PRAC meetings

- **4 days meeting every month**
 - Referrals
 - Signals
 - Risk Management plans
 - Periodic safety update reports (PSUR)
 - Post authorisation safety studies (PASS)
 - Renewals of the Marketing Authorisation, Pharmacovigilance inspections, requests from CHMP, organisational matters'
- **Agendas, minutes and highlights on EMAs web**

Some examples from PRACs work on referrals 2013 of particular interest from a communication perspective

- **Diklofenac – New contraindications and warnings due to cardiovascular risks**
- **Codein – Restricted use in treatment of pain in children and some adults due to risk of serious respiratory depression**

Some examples from PRACs work on referrals 2013 of particular interest from a communication perspective

- **Shortacting beta-agonists - oral and suppository forms - shall no longer be used to treat premature labour due to risk of cardiovascular adverse drug reactions**
- **Combined hormonal contraceptives – update of information on VTE risk for different generations of p-pill**
 - Valuable input from CPWP/PCWP on the communication package

EMA to follow up your experience - how do we co-operate in the best way?