

# **PARACETAMOL USE AT THERAPEUTIC DOSES IN SEVERE HEPATIC IMPAIRMENT OR SEVERE HAEMOLYTIC ANAEMIA**

## **Summary of Assessment Outcome agreed by PhVWP in July 2011**

*Doc. Ref.: CMDh/PhWP/032/2011  
September 2011*

**Headline:** Paracetamol 500mg – review of scientific literature suggests that SPC guidance on posology and warnings & precautions are sufficient for use in patients with 1) pre-existing severe hepatic impairment or 2) severe haemolytic anaemia / G6PD deficiency when used at therapeutic doses

Following completion of a decentralised licensing procedure for generic Paracetamol 500 mg effervescent tablets (Accord Healthcare) it was agreed that the available data should be reviewed regarding the use of paracetamol at therapeutic doses in individuals with severe hepatic impairment or severe haemolytic anaemia to determine whether use in these conditions should be strictly contraindicated or whether use was acceptable subject to inclusion of appropriate warnings & precautions about the risks. The PhVWP reviewed and assessed the available scientific literature on the safety of paracetamol use at therapeutic doses in patients with pre-existing severe hepatic impairment or severe hepatic haemolytic anaemia, to advise on what type of safety recommendations would be most suitable. Taking into account the limitations in the data and the safety of alternatives to paracetamol in these populations, the PhVWP concluded that there was insufficient evidence to support a contraindication in either severe hepatic impairment or severe haemolytic anaemia. Retaining the current information in section 4.2 and in section 4.4 of the SPC for the paracetamol product authorised to Accord Healthcare was recommended, as this adequately reflects the evidence and provides sufficient information on minimising the potential risks in both populations. PhVWP advised that no further regulatory action is necessary on safety grounds in relation to this issue. However, the same wording could be applicable for all 500 mg paracetamol products.