

Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure No: EMEA/H/A-31/1365

Domperidone containing medicinal products

The following CMDh Members support the divergent position appended to the PRAC recommendation on domperidone containing medicinal products dated 06 March 2014, as stated below:

CMDh members expressing a divergent position:

Virginie Bacquet (FR)	24 April 2014	Signature:
Sandra Petraglia (IT)	24 April 2014	Signature:

Divergent statement from PRAC members

We, the undersigned

Agree that the proposed minimisation risk measures are sufficient to ensure a favourable benefit-risk ratio in adults.

However, we stand against its use in the paediatric population under 12 years of age and adolescents weighing less than 35 kg. This position is based on the potential risk and the insufficiency of available data in children, where the efficacy relies on a long-lasting experience associated with an extrapolation of adult population data. At the new proposed doses the effectiveness is not established and the cardiac risk is not excluded.

In addition, the misuse in children, especially in infants, is a major issue which could be definitively avoided by a contra-indication. Indeed, the medical need for this product in the treatment of acute nausea and vomiting in children has not been clearly established.