



Response to ARM23 ([Request to reclassify Calpol Infant Suspension, Calpol Sugar Free Infant Suspension and Calpol Six Plus Fastmelts from P to GSL](#)) from the NPA.

Response of the National Pharmaceutical Association to ARM 23

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 23 on proposals to reclassify Calpol Infant Suspension, Calpol Sugar free Infant Suspension and Calpol Six Plus Fastmelts. The NPA has concerns regarding this proposal, as the organisation is not convinced that the products can be used safely and effectively without the supervision of a healthcare professional.

The changes to the Prescription Only Medicines Order in 1998, regarding the sale of paracetamol, highlighted the Government's views on the safety of paracetamol. It was felt necessary to reduce the pack sizes available for sale to the public to prevent both accidental and intentional poisoning. It seems anomalous to us, therefore, that the Government now intends to increase the availability of paracetamol for use in children. This would certainly confuse the public who have just got used to the message of "caution" which was given when paracetamol sales were restricted.

The legislation restricting pack sizes of paracetamol has been successful in reducing overdoses. The Centre for Suicide Research at Oxford studied statistics on paracetamol and aspirin overdosage from before and after the 1998 legislation and concluded that the annual number of deaths from paracetamol overdoses decreased by 21%, liver transplant rates after paracetamol overdosage decreased by 66% and the number of serious overdoses decreased by 17%.ⁱ Prior to this legislation, paracetamol overdose accounted for 30- 40,000 hospital admissions and 100-150 deaths each year.ⁱⁱ In 2001, paracetamol overdose mortality figures showed the lowest mortality for nearly 20 yearsⁱⁱⁱ. In our opinion these figures may increase once more if liquid paracetamol becomes more widely available.

In 1994 Airedale General Hospital launched a campaign to reduce the high number of hospital admissions in young children which arose from accidental paracetamol ingestion^{iv}. In this hospital between April 1992 and March, 1993, out of 289 admissions to the children's ward as a result of accidents, 12% were linked to the ingestion of drugs and 61% of these were due to paracetamol.

Unintentional overdose is known to occur when patients take more than one preparation containing paracetamol. When paracetamol preparations are supplied in the pharmacy the pharmacist and their staff will check that the patient is aware that the product contains

paracetamol and will remind patients or their carers to avoid taking other paracetamol containing products concurrently. Such advice is not available in non-pharmacy outlets. We believe the likelihood of children inadvertently receiving an overdose by being given two products containing paracetamol would be increased if liquid paracetamol was to be available from outlets other than pharmacies.

Use in infants under 3 months

It is of particular concern that the proposed GSL product will also carry dosage information for infants under 3 months for post vaccination fever and also other causes of fever or mild to moderate pain. There could be many possible causes of fever or pain in an infant under 3 months, including many more serious conditions. Infants of this age would need to be assessed by a healthcare professional. In a pharmacy the pharmacist and their staff will be able to advise the parent of an infant with fever or other symptoms and will refer the parent to their practitioner where necessary.

Rationale for reclassification

The application states that as the product is already classified as a GSL product when provided in packs of 20 x 5ml sachets the difference in legal status is based on packaging format. However overdose, whether accidental or intentional, would be more likely to occur if the product is available in larger liquid volumes such as 70ml or 100ml bottles. In addition when the product is available in sachet format the potential for error is reduced as the correct dose has been already calculated.

In conclusion, we believe that making paracetamol products for children more widely available outside pharmacies is not in the interest of public safety and is out of line with the Government's recent policy on paracetamol pack sizes. It is likely to have cost implications for the NHS if there are an increased number of inquiries to the Poisons Centres or presentations at accident and emergency departments due to accidental overdose. This proposal will give out mixed messages to the public about the Government's policy on paracetamol and lead to confusion regarding the safety issues surrounding paracetamol.

We hope you take our comments on board.

ⁱ K Hawton et al Effect of legislation restricting pack sizes of paracetamol and salicylate on self poisoning in the UK BMJ 2001 322: 1203-1207

ⁱⁱ CSM Current Problems Volume 23 September 1997

ⁱⁱⁱ Letter from director of the Paracetamol Information Centre Pharmaceutical Journal Vol 267 No 7176 p778-781

^{iv} Campaign to reduce accidental paracetamol ingestion in children. Pharmaceutical Journal 1994; 253:638