

MHRA consultation document: ARM 54
REQUEST TO RECLASSIFY A PRODUCT FROM P TO GSL
Calpol Six Plus Suspension Sugar Free
Response of the Pharmaceutical Society of Northern Ireland

Protecting patient safety is the primary objective of the Pharmaceutical Society of Northern Ireland. The Society therefore has certain concerns about the reclassification of any Paracetamol product from P to GSL.

The Society notes:

- Paracetamol is a very useful analgesic (alone or in combination).
- Paracetamol is also is a popular antipyretic.

However, the Society also notes:

- Paracetamol is the commonest cause of acute liver failure¹
- About 500 drug poisoning deaths involving Paracetamol (acetaminophen) occur every year in England and Wales²
- A recent report from the Southwark Coroner's Court into the death of Deborah Lynne Robinson of Limavady, Northern Ireland. The report recorded a verdict of accidental death due to liver failure, caused by an unintentional paracetamol overdose.
- Paracetamol packaging recommends no more than 8 tablets to be taken in a 24 hour period to stay within safe dosage levels.
- Ms Robinson is reported to have consumed 16 and a half Paracetamol tablets in a 48 hour period – only half a tablet over the recommended safe level.,

¹ Fagan E, Wannan G. Reducing paracetamol overdoses. BMJ Editorial; December 1996

² Oliver Morgan , Clare Griffiths , and Azeem Majeed. Impact of paracetamol pack size restrictions on poisoning from paracetamol in England and Wales: an observational study. Journal of Public Health, January 2005

- Some adults are known to take Calpol as a preferable alternative to paracetamol tablets.
- The MHRA statement: “*Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks*”

Therefore, in respect of the potential dangers posed by Paracetamol products, before *any* reclassification of a Paracetamol product from P to GSL, **the Society recommends:**

- Any reclassification should be based on a sound evidence profile that patient safety is not being unduly put at risk
- Any reclassification should be accompanied by a robust review of safety information on the packaging
- The need for parents to speak to their pharmacist if their child is taking other medications should be prominently displayed on the packaging