Pfizer Australia Level 15-18 151 Clarence Street Sydney, NSW, 2000Australia

18 September 2019

Medicines Scheduling Secretariat
Office of Medicines Authorisation (MDP 122)
PO Box 100
Woden ACT 2606
Australia
Medicines.Scheduling@tga.gov.au

Dear Sir/Madam.

Re: Proposed amendments referred for scheduling advice to ACMS #28

Item 1.1 Paracetamol

Pfizer Australia Pty Ltd (Pfizer) appreciates the opportunity to provide comment in relation this agenda item.

Under "Reasons for Proposal", the available paracetamol liquid preparations are listed, including: "32.5 mg/mL paracetamol + 1 mg/mL dextromethorphan (intended primarily for use in children, are currently available as a Pharmacy Medicine (Schedule 2))."

For the purposes of accuracy of the public record, we wish to clarify that it is incorrect to state that this product was "intended primarily for use in children". The TGA approved artwork provided dosage instructions limited to adults and children 12 years and over, and included a Warning Statement "Do not use this product in children under 12 years of age".

Should you require any additional information or clarification, please do not hesitate to contact me directly.