1.The European Medicines Agency suspended the sale of MR paracetamol in EU member countries altogether, and New Zealand's Medsafe New Zealand's Medsafe, at its Meeting on 26th. April resolved that "modified release paracetamol be reclassified from a pharmacy-only medicine to a restricted medicine".(equivalent to our S3 Poisons Classification").

2.The complex and unpredictable pharmacokinetic profile of MR paracetamol following an overdose means that the continued availability of MR paracetamol in pack sizes of 96 caplets as a Schedule 2 medicine poses an unacceptable to risk to the Australian population.

3 .Up-scheduling MR paracetamol to Schedule 3 will provide an opportunity for pharmacists to utilise their expertise to counsel patients on the importance of not exceeding a dose of 6 tablets per day, whilst still preserving OTC access to these products, as well as advice regarding the use of paracetamol with other analgesic products, including potential drug interactions and all other relevant aspects of analgesic medication management.

4. Given appropriate pharmacy counselling**, I am not in favour of reducing the pack size, as I believe this would unnecessarily limit consumer availability of the current range of the non-prescription medications, for the responsible and informed use of analgesics by patients for pain relief, especially in the light of the recent up-scheduling to Schedule 4 of Codeine products**.

5. **Updates to the Product Information, with appropriate advice to health practitioners, need to be made by the manufacturers of modified release Paracetamol products,** which incorporate the clinically agreed appropriate method for managing overdoses of MR Paracetamol Tablets.

6. An additional emphasis in bold letters needs to be added to the CMI for MR Paracetamol products, for the wording in the section: "How much to use", where it currently states:"
Adults and children aged 12 years and over:
*Do not take more than 6 caplets in 24 hours.
*Not recommended in children under 12 years.
* i.e. My suggestion is that these two statements need to be in bold letters.

7. The Poisons Schedule change should be followed by appropriate updated practice guidelines by medical and pharmacy post-graduate educational groups, in addition to a widely-distributed summary by NPS Medicine Wise on dosage recommendations and agreed management of overdosage of, MR Paracetamol**.**

8. Additional Note:How proposed change will impact me:

I do not have any pecuniary or other interests in the outcome of the proposed changes.

However, as a pharmacist of some 55 years, having worked in all areas of community and and senior hospital pharmacy practice, I have a professional interest in contributing to ensuring that prescription and non-prescription medications incorporate agreed best practice standards regarding the balance between optimum safety and ready availability of medications, within the framework of Poisons legislation, and consensus peer-reviewed professional standards.

Also please note: **in January 2017, I was appointed as a specialist advisor to contribute to TGAs key regulatory functions. However, I have not been requested to forward these public comments in that context , and the issues raised above are presented solely as my own individual comments , submitted out of professional interest and patient safety concerns.**

Ronald Batagol, PhC,FSHP,AGIA, Dip.Jnl.