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Re: Consultation: Referral of proposed amendment to the current Poisons Standard to the meeting of the ACMS, March 2019

AFT Pharmaceuticals Pty Ltd. ("AFT") welcomes the opportunity to make a public submission in regards to the proposed amendment to the current Poisons Standard of Paracetamol in Australia.

AFT supports the update of the terminology "slow release" to "modified release" in the Poisons Standard.

AFT acknowledges the safety issues identified by the European Medicines Agency. However, we would like to request that the Therapeutic Goods Administration review the reported safety issues in Australia and New Zealand as well, prior to arriving at a decision. Based on our Periodic Safety Update Report for Paracetamol Osteo-Tab (Paracetamol modified-release tablet, 665 mg per tablet, AUST R 202406 and AUST R 202407), it shows that there has been no Adverse Drug Reactions ("ADRs") since the commencement of the sale in 2013. A total of over 348 million tablets have been distributed in Australia and New Zealand alone over the past 5-year period with no ADRs being reported to AFT.

AFT understands that the proposal is expected to be discussed during the Advisory Committee on Medicines Scheduling's meeting in March 2019. In case of the proposal being accepted and moving forward, AFT would like to request that the sponsors be allowed a reasonable period of time to deplete the released stock with S2 scheduling on its artworks.



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