

21 April 2020
LOC/2020/MSIA/ERYSOL OS-009(1)

Principal Assistant Director
Generic Medicines Section
Centre of Product & Cosmetic Evaluation (PPPK)
National Pharmaceutical Regulatory Agency
Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.

(Attn: Ms. Lim Sze Ne)

Dear Ms. Lim,

Commitment for Post Approval Variation Submission

Product	Active Ingredient	Registration No.
ERYSOL FOR ORAL SUSPENSION 200MG/5ML	Erythromycin 200mg/5ml (as Erythromycin Ethylsuccinate)	MAL19860675AZ

With reference to the above mentioned, please be informed that we commit to submit the variation to remove pack size of 100ml (MiV-N11) after the variation on safety update (MiV-PA2) has been approved by NPRA.

We hereby also commit that the RiMUPs would be submitted to pharmacovigilance unit for evaluation.

We sincerely hope that you will approve our variation on safety update in order for us to submit the committed variation in a timely manner.

Thank you for your consideration.

Yours sincerely,
XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD



Lee Xui Kin
Regulatory Affairs Manager