European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

20 January 2021

Subject: Withdrawal of Dexamethasone Taw Pharma 4 mg/ml & 10 mg/ml, solution for injection/infusion - EMEA/H/H005740

Dear Harald Enzmann,

I would like to inform you that, at this point of time, Taw Pharma (Ireland) Ltd has taken the decision to withdraw the application for Marketing Authorisation of Dexamethasone Taw Pharma 4 mg/ml & 10 mg/ml, solution for injection/infusion, which were intended to be used in the following indications:

Systemic use
Intravenous, intramuscular, infusion
- *cerebral oedema associated with cerebral tumour, neurosurgical procedures, cerebral abscess*
- *cerebral oedema associated with bacterial meningitis (e.g. tuberculosis, typhoid, brucellosis)*
- *anaphylactic shock (after first epinephrine injection)*
- *polytraumatic shock/prophylaxis of post-traumatic acute respiratory distress syndrome*
- *severe, acute asthma attack*
- *initial parenteral treatment of extensive, acute, severe skin diseases like generalised exfoliative dermatitis, pemphigus vulgaris, acute eczema*
- *initial parenteral treatment of autoimmune diseases like systemic lupus erythematosus (especially visceral forms)*
- *active rheumatoid arthritis with a severe, progressive course, e.g. forms that quickly lead to joint distruction and/or with extra-articular manifestations*
- *prophylaxis and treatment of postoperative vomiting*
- *prophylaxis and treatment of cytostatic-induced vomiting as part of antiemetic regimens*
- *treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) who require supplemental oxygen therapy.*

Local use
Intraarticular
- *persistent inflammation of one or a few joints after general treatment of chronic inflammatory joint disorders, active osteoarthritis, acute forms of periarthritis humeroscapularis*

Infiltration
- *(when strictly indicated) non-bacterial tenosynovitis and bursitis, periarthritis, enthosopathy*

Ocular
- *ocular use for non-infectious keratitis, scleritis (except necrotising scleritis), iridocyctltis and intermediate uveitis.*

This withdrawal is based on the following reason:
- *Reformulation activities to remove preservatives are not possible within the timeframe proposed by the EMA.*

Taw Pharma (Ireland) Ltd would like to sincerely thank the EMA as well the (Co-) Rapporteurs for their guidance, support and engagement in the review. Those efforts permitted us to work to effectively progress the application through the review process to date.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website. Yours sincerely,

[redacted]