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PARECOXIB (DYNASTAT)

The Bureau of Food and Drugs would like to announce, after a careful review, the re-introduction of Parecoxib (Dynastat) into the Philippine market.

The following reasons justify the said action:

1. Demonstrated efficacy for short-term (< 3 days) pain control after dental, general, gynecologic and orthopedic surgeries

2. Use of parecoxib decreases demand for opioid analgesics (based on study comparing morphine and ketorolac) by 20-40%

3. Currently approved for marketing in Australia, Singapore and the European Union

4. Rare occurrence of serious skin reactions like Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)

For Parecoxib, the BFAD would hereby recommend the following:

1. Maximum duration of Dynastat administration to not more than 3 days

2. Limit the use in hospitals.

3. Availability in hospital pharmacies only

4. Its use under immediate physician supervision (anesthesiologist/surgeon)

5. Company to conduct postmarketing surveillance study for 3 more years

6. Safety measures that should be instituted and use of checklist to implement these measures before Dynastat can be given:

a. As for patient screening, the conditions that are listed below constitute absolute contraindications (also reflected in the black box warning of the package insert)

- Coronary Artery Bypass Graft (CABG) patients
- Stroke
- Myocardial infarction
- Congestive Heart Failure (CHF) NYHA II-IV
- Uncontrolled Hypertension