

August 16, 2018 Sawai Pharmaceutical Co., Ltd.

Sawai Pharmaceutical Receives Approvals for

Six Compounds with 13 Strengths of Generic Drugs

Osaka, Japan –August 15, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) received approvals by the Ministry of Health, Labour and Welfare for six compounds with 13 strengths of generic drugs. Among the six compounds, four compounds, Mirtazapine, Atomoxetine Hydrochloride, Tramadol Hydrochloride / Acetaminophen and Capecitabine, are approved for the first time as generics.

- * TOARASET[®] Combination Tablets are Tramadol Hydrochloride and Acetaminophen, and are counted as one compound.
- * FREWELL® Combination Tablets are Norethisterone and Ethinylestradiol, and are counted as one compound.

The list of approved products:

1. MIRTAZAPINE OD Tablets 15 mg [SAWAI] / 30 mg [SAWAI],

MIRTAZAPINE Tablets 15 mg [SAWAI] / 30 mg [SAWAI]

· Generic name: Mirtazapine

Indications: Depression / depressive state

•Brand products: REFLEX® TABLETS 15 mg / 30 mg, REMERON® Tablets 15 mg / 30 mg

2. ATOMOXETINE Capsules 5 mg [SAWAI] / 10 mg [SAWAI] / 25 mg [SAWAI] / 40 mg [SAWAI]

·Generic name: Atomoxetine Hydrochloride

Indications: Attention-deficit / hyperactivity disorder (ADHD)
Brand products: Strattera[®] Capsules 5mg / 10 mg / 25 mg / 40 mg

3. TOARASET® Combination Tablets [SAWAI]

· Generic name: Tramadol Hydrochloride / Acetaminophen

•Indications: Non-cancerous chronic pain and pain after tooth extraction that cannot be managed by

treatments with non-opioid analgesics

•Brand products: TRAMCET® Combination Tablets

4. ROPINIROLE Extended-release Tablets 2 mg [SAWAI] / 8 mg [SAWAI],

Generic name: Ropinirole HydrochlorideIndications: Parkinson's disease

•Brand products: ReQuip® CR Tablets 2 mg / 8 mg

5. FREWELL® Combination Tablets ULD [SAWAI]

· Generic name: Norethisterone / Ethinylestradiol

Indications: Dysmenorrhea

·Brand products: LUNABELL® Tablets ULD

6. CAPECITABINE Tablets 300 mg [SAWAI]

· Generic name: Capecitabine

Indications: Inoperable or recurrent breast cancer, colorectal cancer, gastric cancer

•Brand products: XELODA® Tablets 300

E-mail: koho@sawai.co.jp