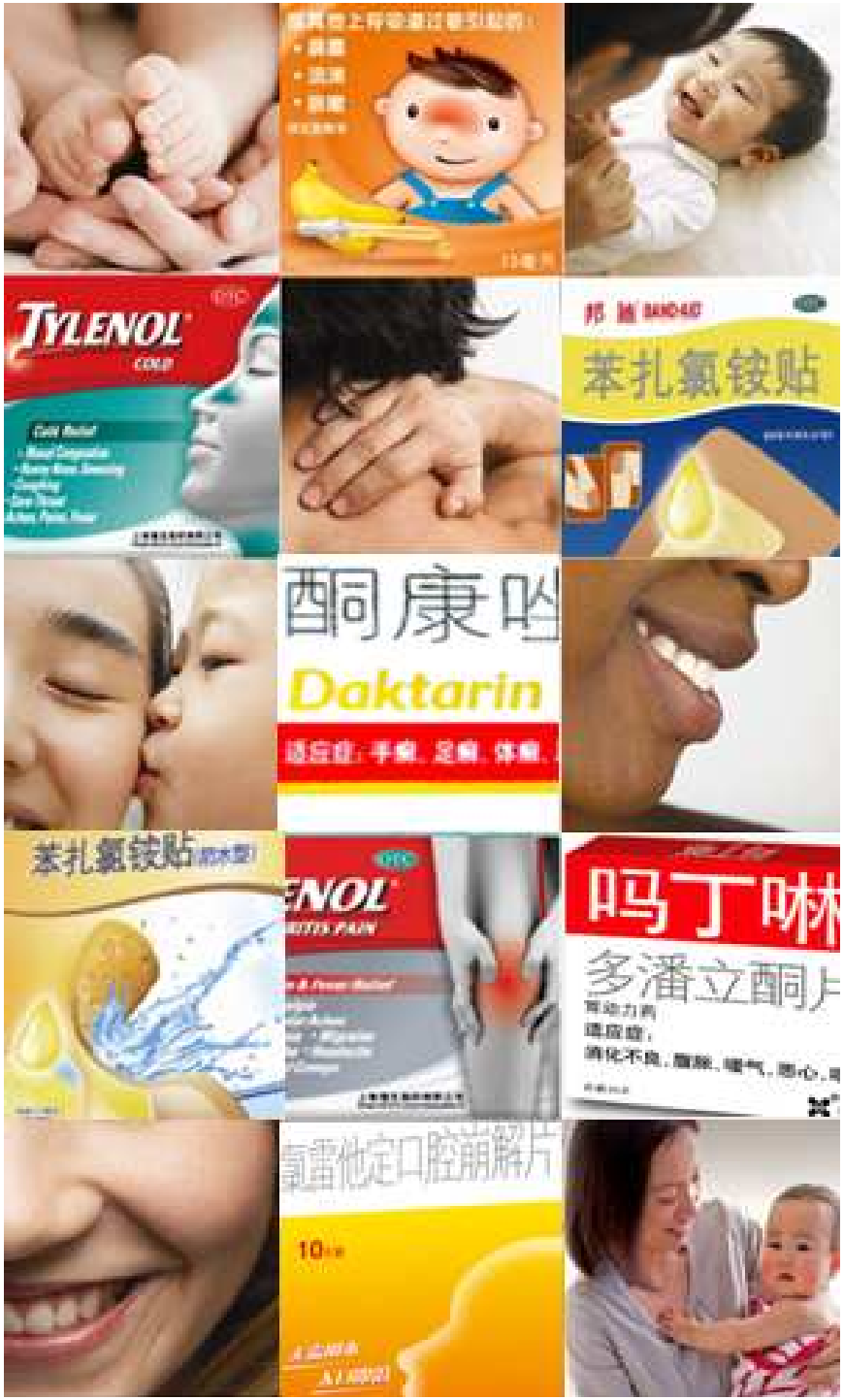
Introduction of OTC switch in China



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Regulatory Affairs of One China OTC J&J

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Outline

- Regulatory History
- Classification
- Switch
- Challenges

Regulatory History

- 3 stages
  - Stage 1: before 1999
    - all drug products could be gotten from pharmacy without prescription.
  - Stage 2: 1999-2004
    - Provision for administration of Rx and OTC products was published in 1999;
    - 6 OTC products' lists were published.
  - Stage 3: 2004-now
    - Notice for OTC switch was published;
    - Establishment of OTC products was changed from screening to switch from 2004.

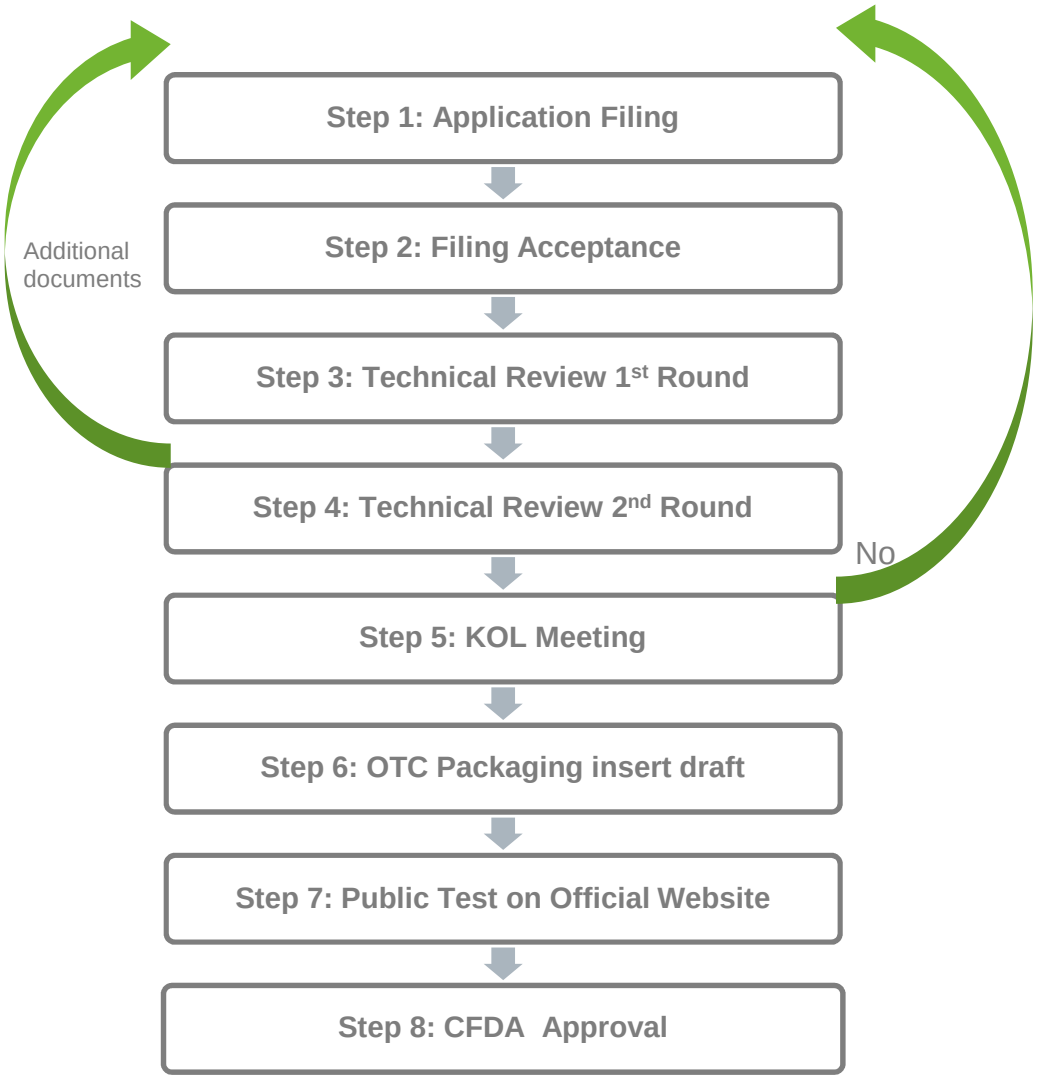
Classification

- Three recognized classes of legal status:
  - Rx (Prescription)
  - Over-the-counter
    - OTC A (Pharmacy only)
    - OTC B (General sales)
  - Dual status

Switch-what medical products can be switched to OTC?

- We can apply for OTC switch for all drug products except for below categories：
  - Drug products with monitor period；
  - Drugs used for emergency or treat for disease which cannot be diagnosed by patients, e.g. cancer.
  - Drugs which is not convenient to administration, e.g. injection.
  - Medical tendance and advice are necessary during treatment with the drug products；
  - Drugs need to be stored under special condition, e.g. low temperature
  - Systemic antibacterial, hormone (except for contraceptive) ；
  - Chinese traditional medicine with toxic ingredients, and safety of the product cannot be proved;
  - API, excipient, Chinese traditional medicine materials；
  - Narcortics, psychotropics and radioactivity drugs；

Switch-what process should be followed for OTC switch?



Switch-what documents are required for OTC switch?

- Summary
  - Application form
  - Content of application documents
  - Application instructions, i.e. the summary of drug development, manufacturing, sales, safety and efficacy
  - Draft of OTC labeling
  - Sample of the drug
  - Certificates, e.g. product license
- CMC documents
  - Specification of the drug product and excipients
  - Quality documents of the drug product, including quality report and stability data

Switch-what documents are required for OTC switch?

- Safety documents
  - Toxicity studies
  - Adverse events
  - Dependence studies
  - Drugs Interaction and affect of food
  - Research and assessment of self diagnosis and medication
  - Research and assessment of extensive use
- Efficacy documents
  - Pharmacodynamics research data
  - Efficacy study data

OTC labeling

OTC logo、external used logo

Product name

Please read PI carefully and administer the drug according to PI or consulting your pharmacist

【product name】
【ingredients】
【appearance】
【therapeutic area】
【indication】
【strength】
【Posology and Method of Administration】
【Undesirable Effects 】
【Contraindications 】
【Special Warnings and Special Precautions for Use 】
【Interactions with Other Medicinal Products and Other Forms of Interaction 】
【Special Precautions for Storage 】
【Nature and Contents of Container 】
【Shelf Life 】
【specification number】
【license number】
【date of the PI】
【manufacturing site information】
please contact with the manufacturing site if there is any question

Challenges

- No clinical trial is required. However, the indication and dose can not be changed
- The drug product OTC status in the world is important reference
- OTC switch for dual status products is ceased
- No clear timeline for OTC switch
  - Normally, CFDA publish OTC list and approved labeling template on their website when the switch application is approved twice a year.
- No exclusivity
  - After publication, all the companies which holding the product license of same product can launch the product with OTC packaging and labeling rather than only the applicant

Thanks!