

Pharmacology Department Requirements for Insert submission

1. Products submitted acc. To Sub- Committee & 296

- Covering letter
- Transmission letter
- Stability approval
- Approved composition.
- Pricing approval
- English & Arabic leaflets
- Approved Reference (**or** Declaration that the submitted insert is the most updated in country of origin **or** Copy of valid Cpp. **For imported products**)

2. Products submitted acc. To 370

- Covering letter
- Technical committee approval
- Stability approval
- Pricing approval
- English & Arabic leaflets
- Approved Reference (**or** Declaration that the submitted insert is the most updated in country of origin **or** Copy of valid Cpp. **For imported products**)

3. Warnings to be added to leaflets of registered products

- Covering letter
- Copy of Final Registration Liscence
- Copy of previously approved insert or an approved reference
- New insert after addition of warning

4. Inserts submitted for Update

- Covering letter
- Payment receipt
- Current insert



- New insert
- Previously approved insert or an approved reference

Note: All declarations should be stamped by the applicant company and signed by the Regulatory Affairs Manager.