Generic Drugs PIL&SPC Creation From Originator (EMC Source)

- Creation is almost copy paste from originator + alignment with SFDA guidelines
- Redact Proprietary information of the originator (licensor, manufacturer)
- you take the main section (medical information you copy-paste)
- leaflet should contain storage condition should be available
    - storage condition should be matching in the artwork, PIL, and SPC & Stability Study
    - Stroage Condition would come form stability study, based on that you'd reflect it in your PIL artwork and SPC
    - storage condition is based on geo zone
        - based on geo zone (store above 30, store below 30, store above 25, store below 25,....)
- pharmacovigilance contact information
- properly translated t arabic (it should not be static google translate it should be contextual)
    - active materials and excipients should be translated properly
        - should be translated into proper scientific names
            - when a word doesn't have a arabic alternative/meaning it should be transliteration
            - should be translated in same way it's translated by all companies in saudi market as approved by SFDA
        - disease, side effects, materials (usually they are not arabic origin)
        - any term that doesn't have a arabic alternative should be transliterated
- for all sections there are clear instructions in the sfda/gcc guidelines

    - also the order in which information is presented in the PIL (this is clearly described in the guidelines and also as available in drug samples directory (this directory contains PILs already approved by SFDA))
- for medical claims you shouldn’t tweak or alter the innovator
    - any medical claim should be supported by evidence (this would require clinical studies and trials)
    - use only what the innovator used
- every generic drug should have Bioequivalence study (context for ai: for this we just need to include it in our review checklist in accordance with guidelines)

The Above will create a Draft for the PIL

After that there needs to be a review and checklist in accordance with the SFDA Guidelines

+Review is done on the Leaflet and SPC

- They need to be 100% (structure and design is different between SPC and PIL but information and context should align 100%)

For review also you need to check again that translation for terms aligns with required as mentioned above or not, also you need to check for words that are connected and shouldn’t be connected

+for review you should compare it with SPC and Artwork

- all the information should align 100% between PIL, SPC and Artwork
    - these three are always tied and aligned together

review is done as checklist before submission based on what’s mentioned for review and most importantly based on requirements from guidelines and requirements for each section