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Date 13/12/2021
Reference: AD (510879/80)

THE RESPONSIBLE PHARMACIST
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Dear Sir/Madam

RE: APPLICATION FOR AMENDMENT: DUPIXENT AND DUBRANTIS- 510879 & 510880

After evaluation of the PI and PIL amendment dated 13 August 2021 sequence 0007 in terms of safety, quality and efficacy, SAHPRA recommend that; the following be approved:

1. Update of the PI and PIL format in accordance with the relevant changes to the Act, General Regulations and current PI/PIL Guidelines (July 2019).
2. Minor editorial changes in the PI/PIL for better professional and patient understanding.
3. Product safety update in line with currently approved SmPC from RRA. MHRA.
4. Safety updates in line with Module 2.5 (Safety evaluation reports) and Module 2.7 (Clinical summaries).

Yours faithfully

KHAMUSI MUTOTI

K.P MUTOTI
BIOLOGICAL MEDICINES UNIT MANAGER