Application of PAAB code s3.1 to study presentations involving dose titration:

Product HV2P is available in two dosage strengths: 15 mg and 30 mg. The TMA states that the recommended starting dose is 15 mg with the option to titrate to 30 mg depending on individual patient efficacy and tolerability.

Case 1a: Trial used a starting dose of 30 mg; trial results are presented in the TMA

Study results can be presented in advertising. The advertising presentation is limited to the content from the TMA. Disclosure of the recommended starting dose should be made; the level of prominence required for this disclosure (e.g. body copy vs. footnote, positioning, etc.) will be assessed based on content/context.

Case 1b: Trial used a starting dose of 30 mg; trial results are not presented in the TMA

PAAB will question this trial as off-label.

Case 2: Trial evaluated the 30 mg dose; patients were appropriately titrated from 15 mg

Regardless of whether the trial is in the TMA or not, study results can be presented in advertising. The dose titration should be captured in the study description.