| **DRUG, SPONSOR, TYPE OF SUBMISSION** | **DRUG TYPE OR USE** | **PURPOSE OF REVIEW** | **PBAC OUTCOME** |
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| **EZETIMIBE + SIMVASTATIN**  ezetimibe 10 mg + simvastatin 10 mg tablet, 30  ezetimibe 10 mg + simvastatin 20 mg tablet, 30  ezetimibe 10 mg + simvastatin 40 mg tablet, 30  ezetimibe 10 mg + simvastatin 80 mg tablet, 30    Vytorin®  Merck Sharp and Dohme (Australia) Pty Ltd  PBS review  (Major Submission) | Hypercholesterolaemia | To present evidence to quantify the compliance benefit provided by the fixed dose combination (FDC) product with the purpose of maintaining the current advice under Section 101 (4AC) of the *National Health Act* 1953. | The PBAC advised the Minister that it was no longer satisfied as to the matters required by subsection 101(4AC) of the Act in relation to the following combination items: ezetimibe with simvastatin, tablets, 10 mg – 10 mg, 10 mg – 20 mg, 10 mg – 40 mg and 10 mg – 80 mg, oral. |
| Sponsor Comment: | The sponsor disagrees with the decision from the PBAC. The sponsor believes that the submission provides the best possible evidence available to meet the CMWG and s101(4AC)requirements i.e. MSD believes that Vytorin provides, for some patients, a significant improvement in patient compliance over alternate therapies. MSD does not believe there is sufficient evidence to overturn the PBAC’s previous decision. |