Thank you for the opportunity to comment on the assessment report. We have only one comment, which is to clarify the licensed indication for topotecan. The assessment report specifies on page 13 that the licence is after failure on 1st line platinum-based therapy:
Paclitaxel (various manufacturers) is licensed for first-line treatment of ovarian cancer in combination with platinum-based chemotherapy, and as second-line treatment of ovarian cancer after failure of standard platinum-based therapy. PLDH (Caelyx®, Jansen-Cilag) and topotecan (various manufacturers) are licensed for the treatment of advanced ovarian cancer after failure of first-line platinum-based therapy.
Please note that there is no specification that 1st line therapy should be platinum-based in the licensed indication, which is: Topotecan monotherapy is indicated for the treatment of patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy.